EXHIBIT K

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

IN RE : ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)	Master File No. 2:12-MD-02327
THIS DOCUMENT RELATES TO PLAINTIFF: Susan Guinn Case No. 2:12-cv-01121	)	

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DEPOSITION OF STANLEY ZASLAU, M.D.
THURSDAY, MARCH 17, 2016

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The Deposition of STANLEY ZASLAU, M.D., a Witness herein, called by the Plaintiff, taken pursuant to Notice of Deposition and the West Virginia Rules of Civil Procedure, by and before Faye Ann Lehman, a Commissioner in and for the State of West Virginia, at The Waterfront Place Hotel, 2 Waterfront Place, Morgantown, West Virginia 26501, commencing at 11:30 a.m. on the day and date above set forth.

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APPEARANCES:

On behalf of the Plaintiff:
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I N D E X

P R O C E E D I N G S

STANLEY ZASLAU, M.D.,
the witness, having been first duly sworn, was examined and testified as follows:

(Deposition Exhibit No. 1 was marked for identification.)

DIRECT EXAMINATION

BY MR. WALLACE:

Q. I'm going to hand you a document that's been marked as Exhibit 1. Tell me if you recognize it.
A. I do.
Q. Does it have your name on it?
A. Yes.
Q. Can you state and spell your name for me.
A. My name is Stanley, S-T-A-N-L-E-Y, Zaslau, Z-A-S-L-A-U.
Q. Do you know why you're here today?
A. Yes.
Q. Why is that?
A. I'm being deposed by you.
Q. In connection with what?
A. In connection with claims regarding a mesh and mesh-based surgeries.

Q. Am I right that you brought a suitcase with you today?
A. Yes.
Q. And what's in the suitcase?
A. The suitcase has medical records and literature, as well as thumb drives that I've reviewed in preparation.
Q. And why did you bring the suitcase full of that material today?
A. So I can refer to it as necessary.
Q. Did you do anything in connection to a request for documents from you having to do with the reports that you've issued in this litigation?
A. Yes.
Q. What did you do?
A. I read it and reviewed them and discussed them with counsel.
Q. And is it fair to say that you've made a diligent and thorough search for any documents that you've been asked to bring today?
A. Yes.
Q. Are you withholding anything?
A. No.
Q. Can you just identify more specifically

what you've brought so we can just note it for the record?
A. I brought articles that I've reviewed in preparation from a variety of different sources. I brought thumb drives with medical records and other articles that were provided to me by Butler & Snow, and I have brought medical records and depositions that I've reviewed for this case and discussion.
Q. And if I understand you correctly, you were asked to look at materials and then provide an opinion in this case, right?
A. Yes.
Q. And if I'm correct, you've provided a -- what is called a general opinion with respect to the safety and efficacy of the TVT device, right?
A. Yes.
Q. But you've also reviewed medical records and other information relating to two claimants, Susan Guinn and Ms. Hendrix; is that right?
A. Yes.
Q. And you understand that my questions today, Dr. Zaslau, are about the general TVT opinions and not those two specific claimants, right?
A. Yes.

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Q. And you understand that after we're done today, that someone will be asking you questions about your case-specific report for Ms. Guinn, right?
A. Yes.
Q. Okay. Thank you. With respect to your general TVT report, it's my understanding from looking at the documents or the reports that you provided that your general opinion is the same -- it was issued in the Guinn case and the Hendrix case, but it's the same for both, right?
A. Yes.
Q. In other words, it's meant to apply to TVT specifically without regard to who the plaintiff might be?
A. Well, if it were a TVT-O case, there's more material regarding TVT-O in some than others. I don't believe that the reports are exact copies of one another. There are sections that are similar, but certainly, other relevant research for TVT-O that was more recent.
Q. Why don't we do this, then, why don't we mark both of the reports separately, just for the record, and then the exhibits, as I understand

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them, are generally the same.
For example, your CV's the same, right?
A. Yes.
Q. Your list of testimony is the same?
A. Yes.
Q. Why don't we mark the Guinn report as Exhibit 2, please.
(Deposition Exhibit No. 2 was marked for identification.)
Q. Do you recognize Exhibit 2?
A. Yes.
Q. What is it?
A. It is the report for the Guinn case.
Q. And, again, at the beginning of that, it has a section that also provides general opinions?
A. Correct.
Q. And if I'm correct, Ms. Guinn had a TVT-O implanted?
A. Yes.
Q. But you're here to testify about the TVT today, right?
A. Yes.
Q. Now, if you look at the -- we're going to mark the next exhibit, and that is Exhibit 3, which

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will be the Hendrix report.
(Deposition Exhibit No. 3 was marked for identification.)
Q. Have you seen Exhibit 3 before?
A. Yes.
Q. What is it?
A. This is a general report for a retropubic TVT, but also is case specific for the Hendrix case.
Q. So, in other words, just so we're clear, even if we're not taking the Hendrix deposition today, you know that you're here by agreement to give opinions on your general TVT opinion?
A. Yes.
Q. And your general TVT opinion is contained in Exhibit 3?
A. Yes.
Q. Let's mark as a group exhibit your CV and your testimony list as Exhibit 4.
(Deposition Exhibit No. 4 was marked for identification.)
MS. ROBINSON: Did you say CV and?
MR. WALLACE: Testimony list.
MS. ROBINSON: As Exhibit 4?

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MR. WALLACE: Yeah.
BY MR. WALLACE:
Q. Do you recognize Group Exhibit 4?
A. Yes.
Q. What is that?
A. This is a testimony -- a history for the last four years and my current CV.
Q. I notice that certain areas are blacked out. Is that your doing or your counsel's doing?
A. Counsel's doing.
Q. With respect to the testimony list, please take a look at it.
A. Um-hmm.
Q. It says "2014 - Edwards versus JNJ"?
A. Yes.
Q. That's a mesh case, correct?
A. Yes.
Q. And do you recall meeting Mark Mueller in giving your deposition in that case?
A. Yes.
Q. Have you reviewed that transcript recently?
A. I have not.
Q. When's the last time you looked at it?
A. Six months ago or more.

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Q. And why six months ago did you look at it?
A. Because that's when I got it.
Q. And so, since then, in connection with preparing your reports in this case, you haven't referenced it?
A. I have not.
Q. The Weaver versus WVUH case; what is that?
A. That was a case -- a prostatectomy case, a prostate cancer case that I was involved in that I was since waived from its involvement and settled.
Q. Oh, so, you were a party to that case?
A. Yes.
Q. And you testified in that case?
A. Yes.
Q. At deposition?
A. At deposition only.
Q. And you were later dismissed from the case?
A. Yes.
Q. And you didn't pay anything, did you?
A. I did not pay anything.
Q. The Stewart versus Bard case in 2014, what is that?
A. Yes. I am the treating physician.
Q. Is it a mesh case?

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A. Yes.
Q. Is it a case that's pending in the MDL before Judge Goodwin, if you know?
A. I do not believe so.
Q. Do you know where it is pending?
A. I do not.
Q. Who, if anyone, has been dealing with you in that case?
A. Matt Teague, T-E-A-G-U-E.
Q. He's from Beasley Allen; do you know?
A. Yes.
Q. So you've had interaction with him about that case?
A. Yes.
Q. Did you provide a report in connection with that case?
A. No.
Q. But you did give testimony?
A. I gave a deposition for that.
Q. And did you offer opinions in that deposition?
A. Whatever questions were asked of me, but I was certainly not an expert. I was a treating physician.

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Q. What was -- did you link the mesh to the cause of Ms. Stewart's injuries?
A. I don't remember the specifics of that because it was some time ago. I'd have to go back and look to the details of it.
Q. Do you recall giving testimony on behalf of Bard in that case?
A. No. I was purely the treating physician, opposed by that counsel.
Q. The final one on the list is Burkhart, B-U-R-K-H-A-R-T versus Life Chiropractic?
A. Right.
Q. What sort of testimony did you offer in that case?
A. It's a treating physician and expert in a case of neurogenic bladder. It's not a mesh-based case. It's a urinary retention case, unrelated to any pelvic floor issues.
Q. So you were retained by one of the parties in the case?
A. As a treating physician, but also served as an expert.
Q. On whose behalf?
A. Patient.

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Q. And so you testified that there was a causal link between the actions of the defendant and the plaintiff's injuries?
A. That's correct.
Q. If I also recall, you have offered testimony in the past having to do with a case involving the Veterans Administration, right?
A. Yes.
Q. So you remember what I'm talking about?
A. Um-hmm.
Q. Can you just give a brief description of that, please?
A. This was a patient who had an unrecognized ureteral injury at the time of an anterior repair. There may have been more procedures in addition to that, but she had a complex pelvic prolapse case. It was unrecognized. She was referred for treatment to our facility, for which we treated her. And it turns out her ureter was ligated during the initial surgery, and subsequently that case had been tried, lost, and then been tried several other times. I'm not sure how that all played out, but it was -- the physician worked in a facility that was a federal facility, so I don't

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know if it was a federal case without a jury.
Q. But as far as you know, the testimony that you've given in the last four years are listed in Group Exhibit 4?
A. Yes.
Q. And is your CV that you provided in connection with your report up to date?
A. Yes.
Q. How much time did you spend preparing your TVT report?
A. About 30 hours.
Q. Are those hours documented anywhere?
A. I just keep a running list of them at the end of the month. I'm involved in multiple cases, so there's a lot of time that's spent each month in reviewing records and writing reports and opinions for a variety of things. So it's a summed opinion --
Q. I'm sorry. I didn't mean to interrupt.
A. It's a summed, you know, time together.
Q. Do you -- based upon your answer, do you have any way to estimate the number of hours or percentage of working time that you spend each month on mesh-related matters?

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A. I'd say the bulk of my free time is based on that. I don't have any other things that are going on. It doesn't mean I'm doing this every day, you know, all hours of the day, but I would estimate that I spend about two hours a day on average doing this related work.
So I may spend up to 60 hours a month doing something, but it can average between ten hours a month, if things are quiet; but if there's multiple cases -- here's these three going on -- and reports, so I could spend upwards of 30 or more hours a month.
Q. Are these the only two cases in which you're working on?
A. These are the only cases I'm working on right now that I've written reports for, but I've reviewed many other cases that are in various other stages or processes.
Q. And you've reviewed those cases for Ethicon?
A. For attorneys for Ethicon.
Q. At the end of the day, though, it's -- your bills are paid by them?
A. Yes.
Q. Do you have a retainer agreement that exists

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in that -- between you and the lawyers or between you and Ethicon?
A. I work with the Butler & Snow group. I don't work with anyone else or any other mesh companies, meaning, like, you know, Boston Scientific or any of those others. I do not. I've only worked exclusively with them.
Q. Just to be clear, Susan is sitting next to you. You'd assume she's part of the group, right?
A. Susan's part of the group.
Q. Okay, very fine lawyer I might add. I just wanted to make that clear.
How much time did you spend preparing for your deposition today?
A. I spent probably about 20 hours of just deposition prep.
Q. Over how much time?
A. Over the last two to three weeks.
Q. And who did you meet with, if anyone?
A. I've spoken with Susan, and I've spoken with other counsel, part of Butler & Snow, part of the group.
Q. Who?
A. Paul Rosenblatt.

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Q. Who else?
A. And I spoke with an attorney, Susan Pope, for the Goodwin case.
MS. ROBINSON: Guinn.
A. Well, no. Susan Pope is the Goodwin case. I've been working on that as well. So you're talking about -- she knows about this as well. There's a lot of folks, as you know, that's involved in this.
Q. That's right. Just so we're clear, because you talk a little fast, when you say "the Goodwin case," you're not talking about Judge Goodwin. There's another case that you're referring to that exists out there that relates to Ethicon?
A. Right.
Q. And the lawyer you identified as Susan Pope is connected to that case?
A. Yes.
Q. You're not from West Virginia, are you?
A. No.
Q. Where are you from?
A. New York.
Q. Brooklyn?
A. Um-hmm.

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Q. And prior to coming to West Virginia, you were a resident in New York, right?
A. Yes.
Q. And if I'm correct, you finished your residency in --
A. 2000.
Q. In 2000?
A. Yes.
Q. And came to West Virginia in 2001 as an assistant clinical professor, right?
A. Assistant professor, yes.
Q. What's that mean?
A. Well, I'll tell you, in between I spent a year in -- achieving advanced training in neurourology and voiding dysfunction in Brooklyn at Long Island College Hospital as an assistant attending. So essentially an additional year of training, a fellowship year. And then I came for an academic position at WVU as an assistant professor.
Q. Right. An assistant attending, though, just to be clear, is not a fellowship?
A. It is not. That's correct. But this year was meant to be additional training, so additional

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training in neurourology. Back at that time, there were very few formal fellowships, so if you wanted additional training in this area, you could be employed by a hospital and focus in those areas, so that's what I did for that year, and then brought that knowledge to WVU the following year.
Q. Who recruited you?
A. To where?
Q. West Virginia.
A. There was an advertisement looking for someone who had done the things that I do, and I had contacted Dr. Stanley Kandzari, who was the chief of urology at the time, and we spoke, and I came to interview, and I thought it was a great opportunity.
Q. And you've been here ever since?
A. Um-hmm.
MS. ROBINSON: Say "yes."
A. Yes.
Q. Let's go back to what your role was in 2001 for a moment.
A. Okay.
Q. I don't think that's clear.
What did you do as an assistant professor?

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A. When you are an assistant professor, you're a full member of the faculty, and so your responsibility is patient care, surgery, and call responsibilities. But my focus and goal was to build a center for voiding and sexual dysfunction for the people of West Virginia, using knowledge from my additional year of training and from Mount Sinai and bring that here and build something that didn't exist in our state.
So that's when I came here, and I started to build that center of excellence for the center for voiding and sexual dysfunction.
Q. And to be clear, that had nothing to do with mesh, right, between 2001 and 2004?
A. No. I mean, well, these were things that we had done at the time, certainly. We've done mesh since 1998 as a resident, but coming here to build this had nothing to do with mesh.
Q. That's all I'm trying to make clear, that the work that you did between 2001 to 2004 to try and build this center that you're describing was not mesh-related?
A. That's correct.
Q. And as I understand it, you became -- you

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had various titles all the way up to being named as a professor in 2010, right?
A. Yes.
Q. And I take it that between 2001 and 2010, you received pay raises?
A. Yes.
Q. And that with the change in titles that you received in those intervening years, that that's typically when the pay raises occurred, right?
A. No. They can happen annually. You know, we're salaried employees, so our salary is dependent upon normative numbers that are used nationally for academic professors, and so there may be a raise each year. Usually it's equivalent to what would be a standard of living for that salary level. And the pay raise from -- actually, from rank is actually very little. It's really more -- the way our system is based, you can be a full professor, but you're really compensated more based on your clinical productivity and the national norms.
Q. Between 2001 and 2010, would you consider yourself in private practice?
A. No.

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Q. What would you consider yourself working in?
A. Academic practice. Full-time academic.
Q. So at no time between 2001, when you came to West Virginia, to 2010 were you ever in private practice?
A. Not at all.
Q. And to carry that forward, between 2010 to today, at no time have you been in private practice, correct?
A. That's correct.
Q. You would consider yourself an academic practice from 2001 to the present?
A. Yes.
Q. And as an academic, are you paid by -- and forgive me for not knowing, but are you essentially paid by the taxpayers?
A. Our salary comes partially from the state, and our salary also comes from the university.
Q. Which is the university is funded in part by the state, correct?
A. Well, the university part is more the medical school part, which is the practice plan. So there's a portion of our salary is state funding and a portion of our salary is practice

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funding.
Q. But whether or not you treat patients, you're still not engaged in what you would call private practice, right?
A. Not at all.
Q. Thank you. You've listed that you're a certified Six Sigma Black Belt?
A. Um-hmm.
Q. What is that?
A. Six Sigma is a methodology of improving process and flow through a variety of business systems. I took that as an online course in conjunction with completing my MBA in 2005, just to have knowledge of that system to help better further our healthcare system, our WVU healthcare system to be more economical, to be more oriented, so that we can undertake tasks in a logical manner, reduce waste, improve productivity across the institution.
Q. And just so we're clear, you mentioned an MBA program. You took courses both at -- in West Virginia and at the University of Tennessee of Knoxville with respect to an MBA, right?
A. Yeah. The WVU program was just a one-month

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course several evenings a week, just to kind of wet your whistle and get your feet wet with this. And then the 2005 was an online program with some weeks on campus to achieve the MBA over a one-year period.
Q. And would you agree with me that that relates to the business of healthcare?
A. It relates partially to the business of healthcare. It also relates to the understanding of how to improve workflow and how to make a better healthcare system. It's not all about money, you know. Certainly money, you think MBA, you think money, but it's also about improving your processes and improving patient experiences and physician experiences through a system.
Q. Well, in discussing money for a second, why don't we move on.
As someone in academics, you're well aware of the issue of bias, right?
A. Um-hmm.
Q. What does that mean to you?
A. Bias is a curbed opinion or a swayed opinion based on some circumstance.
Q. And I don't want to retread old ground

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that you've already testified about, but it's my understanding that you agree that it's not a good idea to induce physicians to buy a product on anything other than science and good medicine, right?
MS. ROBINSON: Object to form.
A. Say that again.
Q. Well, let me preface where I'm going. I don't want to retread your prior testimony, for example, that you gave in the Edwards case. But I just want to explore this issue of bias with you a little bit more, so that's why I'm asking this question. So what I'm saying is -- let me start over.
You agree with me it's not a good idea to induce physicians to buy products from a medical device manufacturer based on anything but science and good medicine, right?
A. I don't know what you mean by "induce." What does that mean?
Q. Well, you used the word "induce" in the Edwards deposition, so what do you think it means?
A. I don't remember the details of that. If you'd like to show me that, I can read you what I

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had written.
Q. I don't want you to read me what you wrote. I want you to tell me what you think "induce" means as it relates to physicians and healthcare and bias.
Can you do that?
A. I'm not sure where you're going with this, and I don't know --
Q. And I'm not trying to be flippant at all. It doesn't matter where I'm going at this point. What I'm asking you for is your understanding of the word "induce."
It's your understanding. It's not mine. And you've used the word before, in all fairness.
A. Okay.
Q. So just exploring generally this idea of bias, which I think you've had some things to say about and agree with me that it's not a good idea to, for example, take a physician on an exotic trip simply to get them to buy a product, right?
MS. ROBINSON: Object to form.
A. Well, now, I understand what you're saying with the word "induce." You know, induce could be to hint or to suggest or to gently nudge and say,

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"We'd like you to do something." So when you use the word "induce" in terms of trips or large monetary things, then, no, it shouldn't be done.
Now, if induce means that we'd like to pay for your expenses to go to a meeting to learn something, I think that's a reasonable thing.
Q. In fact, you've heard about trips where physicians have been taken in an attempt to get them to induce -- to get them to buy a certain product from a company, right?
A. I've heard about that, yes.
Q. And you don't agree with that?
A. I don't think that that should exist in healthcare.
Q. And you would agree with me that a company, for example, a medical device manufacturer, shouldn't pay for a study based upon the outcome of that study?
A. I don't know the specifics of what you mean by that. What do you mean by that?
Q. Well, let me give you an example.
If you're running a study at your center, you shouldn't be paid based upon the outcome. The outcome should be whatever it's going to be with

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respect to the study, right?
MS. ROBINSON: Object to the form.
A. Well, paid by who and for what?
Q. You don't understand what I'm asking?
A. No. No. I don't understand what you're trying to say. Try again.
Q. Because we're being polite to each other, I will try again.
Do you believe it is appropriate for a medical device manufacturer to pay, for example, a doctor who is running a clinical trial based upon the outcome of that clinical trial?
MS. ROBINSON: Object to form.
A. Not based on the outcome. Based on the materials that are needed to conduct the study, if it were a product and they provide a product for it. If it were cost-related to undertaking the study and coordinators or research or imaging studies or things like that, yes. But based on an outcome, a defined outcome that you have to achieve a certain thing beforehand, that's a different story.
Q. What do you mean by "that's a different story"?

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A. Well, I don't think it's appropriate for someone to be paid for something and require them to achieve a certain outcome. In other words, "You have to have a 100 percent success rate of some procedure, or we're not going to fund your procedure." I don't think that that's appropriate.
Q. Well, what if you're paid a bonus if you get a 100 percent success rate?
A. You could be paid a bonus.
Q. Do you think that's appropriate?
A. It could be, based on outcomes that were discussed, mutually discussed before a trial began, if people had done that. And that's just the industry paying for something. That's not published in a journal in that way.
Yeah, I mean, now, if something like that is published and that support is not mentioned, that's inappropriate. But certainly, they can be funded based on the agreement between two people.
Q. So you think if somebody was paid a bonus if they had, for example, no complications, they received a substantial bonus, you think the fact that there is a bonus and the amount of that bonus should be disclosed in the study once it's

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published?
MS. ROBINSON: Object to form. I don't know if that correctly states his testimony.
A. Yeah, I don't know. These are things that have to be discussed between industry and the individuals undertaking the study. They can discuss, "This is the sum of money that we're giving you, and these are the outcomes that we're looking for, and if these are achieved, these may be compensated in some way." I can't put a monetary value. I would not do that, and I wouldn't engage in that, personally.
Q. Why not?
A. Because I want to be involved in randomized trials. I want to be the one doing the randomizing. If I'm sponsored, I just want to be sponsored for expenses or things that are related to that. That's just my bias. That's my opinion.
Q. Okay. So let's go back and answer my question, though. What I was trying to get at was whether or not you thought -- whether or not I was correct in understanding you, that if you are paid a bonus based for a 100 percent success rate in a

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clinical trial that is later published, that the amount of that bonus and the fact that there is a bonus should be disclosed in the publication?
A. Actually, now, with disclosure statements for our own societies, those numbers are disclosed, if somebody's receiving research money and how much that is and for exactly what that is.
Q. I'm not talking about now. I'm talking about your opinion as it exists. What do you think about it?
A. I think that now, that that's how things should be.
Q. Do you think that it's appropriate to do that five years ago?
A. I think that's appropriate to do that five years ago.
Q. Why?
A. Because when you interpret information, you want to know, was it sponsored, and if so, what level of sponsorship was it and what was the involvement of the participants.
Q. And all I'm trying to get at is that you and I agree that if a physician who is conducting a clinical trial is paid a bonus based upon a 100

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percent success rate with respect to that clinical trial and the results of that trial are published, that there needs to be full disclosure with respect to the bonus in that amount, right?
MS. ROBINSON: Object to form. Asked and answered.
A. I told you that their involvement needs to be disclosed.
Q. When you said "their involvement," you mean the bonus?
A. The financial support. I'm not saying that they have to list the amount of what it is. I think they need to list that significant funding was provided from this company for this research, or so and so has this agreement -- this investigator has this agreement with this industry.
Q. In other words -- let's go to this case. Ethicon, if they're paying for a study, that needs to be disclosed?
MS. ROBINSON: Object to form.
A. I don't know. If they're paying for the study in what way? So they're sponsoring the -- a study in question? It should be disclosed if they're sponsoring a study.

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Q. You've given testimony about ghostwriting before, right?
A. Yes.
Q. And what do you think of it?
A. I think that writers can help others write manuscripts or papers, and certainly that happens.
Q. Writers can help others. What do you mean? Be more specific, please.
A. In other words, you have a paper that's written. It may be written by someone else at another level. It may be from industry. It may be -- may be someone who's your lab instructor who you work with, or your lab, you know, faculty member, and they're writing a paper and you're part of it and you'll offer your contributions and opinions to it. But you need to have -- take ownership for that material if you're part of it.
Q. What do you mean by taking ownership?
A. Well, if your name is on it, that means that you would agree with what's being said.
Q. If a company representative has made editorial changes to an article, should that be disclosed in the final publication of the article?
A. How do we know -- I don't know who they were

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and how they did that or why they did that.
Q. My question's much more simple. I'm not asking why they did it or those sorts of things. I'm just asking you a much more basic question. Can you answer it?
A. They probably -- it would depend on the specifics of what they edited. You know, did they edit and say that no one had any erosions in a case when they actually had ten erosions? Then that's faulty. Depends on what they edited. Is it a minor edit? Is it a complete misrepresentation of something?
Q. So, in other words, if they provide information or alter information, that probably should be disclosed?
MS. ROBINSON: Object to form.
A. If they alter information that would have a significant impact on someone's interpretation, that would be important to know.
Q. Let's move on. You were a Bard Uretex user, correct?
A. Um-hmm.
Q. Is Uretex spelled U-R-E-T-E-X?
A. Yes.

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Q. And what did you use that product for?
A. I used that for suburethral slings.
Q. To treat stress urinary incontinence in women?
A. Yes.
Q. And when I use the acronym SUI, you know I'm referring to stress urinary incontinence, correct?
A. Um-hmm.
Q. And it's fair to say that before 2004 you were a Bard Uretex user and not a TVT user, right?
A. I used them both.
Q. Are you sure about that?
A. Yep.
Q. Have you ever testified differently?
A. I've -- I used a lot more Bard than I had used TVT for a short period of time, but I used TVT as a resident and in some of the other cases that were done in working with our gynecology faculty, if they were going to use that or the resident wanted to use that, we would use that. But I did use Bard for quite a bit of time from 2001 to 2004 or so.
Q. And I'm not suggesting anything, but it sounds like you may have explained things a little

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bit differently before. So let me state what I understand, and you tell me whether I'm right or wrong.
I'll make it simple. Before 2004, you were primarily a Bard Uretex user when you were the surgeon performing the stress urinary incontinence surgery, correct?
A. That's correct.
Q. And TVT was used, for example, at some points when you were a resident?
A. Sometimes when I was a resident and also working with a -- gynecology colleagues who we'd worked with as well.
Q. And that was my next question, so let me ask that in the next sentence.
What changed in 2004 that caused you to start using Ethicon products?
A. Well, the Prolift mesh had come out as well. The obturator approach had certainly changed the traditional way of doing TVTs to an easier, more simplistic way of approaching things, and if we can avoid potential for bladder injury, I think that would be good because with the Uretex, it was a little higher incidence of that.

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Also, I thought the quality of the mesh would be better and easier to implant. I like the concept of trocar-based that's similar to Prolift in that the material -- the materials were easy to use, easy to work with.
Q. What was it about the quality of a TVT mesh versus a Bard Uretex mesh that caused you to change your --
A. I thought it was softer. I thought upon implantation I liked how the mesh would sit in its appropriate place, and it was very easy to do. It was very easy and quick. It avoided the risk of bladder injury, especially when the obturator approach changed a lot of the things that we do. Using the obturator fossa really has cut down on risk of bladder injuries, risk of postoperative pain, risk of voiding dysfunction.
Q. In fact, you'd agree with me that the TVT-O was invented to avoid some of those risks that the TVT presented, which included bladder injuries?
A. It certainly would improve those risks, yes.
Q. Do you have partners in your academic practice?
A. Yes.

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Q. How many?
A. We have, myself now included, five.
Q. And what does having a partner mean to you?
A. It means you work together.
Q. You share information?
A. About patient care.
Q. Do you share information about complications?
A. We do.
Q. And do you share information that may come up in literature?
A. Yeah. Well, part of, you know, journal clubs and conferences, yes.
Q. In other words, you share healthcare information with each other and expect your partners to candidly share information with you when they discuss it?
A. Um-hmm.
Q. How many years of experience do you have with these partners?
A. With our longest one, 15.
Q. You believe Ethicon's a partner of yours, right?
A. Yes.

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Q. And you expect the same from Ethicon, that if it has information about its products that may impact on your delivery of healthcare, you want to know that information?
A. Right.
Q. What other surgeries have you done to treat stress urinary incontinence?
A. I've done pubovaginal slings. I've done Raz needle suspensions, Pereyra and Stamey needle suspensions. We've done certainly slings. We've done injections of material into the bladder neck. I've assisted with MMKs and Burches when we do open things with the gynecologists, only if they've asked me to help them for some pelvic reason. But really, just you're helping them and it's their procedure.
Q. Do you ever have a complication with a patient under general anesthesia?
A. Such as -- you can have any complication, sure.
Q. I guess I'm asking a more specific question. Have you ever had a complication during surgery with a patient that had to do with the anesthesia being delivered?

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A. I have not, no.
Q. Now, with respect to any of these surgeries that you performed, including those with polypropylene mesh, it's important for you to have scientific data before you implant that product, right?
A. Yes.
MS. ROBINSON: Object to form.
A. Yes.
Q. Or perform the procedure, if it's only procedure-based?
A. We'll perform it, yes.
Q. And you wouldn't just implant a device or do a procedure on a woman without having that data, correct?
MS. ROBINSON: Object to form.
A. The data is important, but understanding the procedure that you're going to do and how does it relate to things that you've done already, experience from lectures and national meetings on this, is certainly important, as well, so it's a combination of things.
Q. And those -- the combination of those things, including the data supporting the safety

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and efficacy of the procedure, would apply to either a procedure or an implant, right?
A. Combination of things, yes.
Q. And with respect to the use of Ethicon mesh, you would want to know that your healthcare partner, Ethicon, gave you the necessary information to make the right decision when deciding to use the TVT, right?
MS. ROBINSON: Object to form.
A. I would want to know the pertinent information that relates to me, yes.
Q. And what type of information did you look at to satisfy yourself that the TVT was safe and effective when you started using it in your own surgeries in or about 2004?
A. I'd look at the instructions. I'd look at the presentations that were done at the AUA about that time, what abstracts were presented, information from other colleagues on an academic level, you know, if we had a regional meeting and these things were discussed, certainly, these things would come into play.
Q. What else?
A. And your personal bias. I think switching

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from Bard to switching from GYNECARE is actually very easy. It's an easier product to do. It follows the same things I've been doing. At that point in 2004, I've been doing this for eight years already, including my residency. So here, all of a sudden, there's a better product, it's easier to use, and it's very straightforward.
Q. Did you rely on information from Ethicon besides the instructions for use?
A. No.
Q. Why not?
A. Didn't need to.
Q. Why not?
A. Because it's just a variation of what I've been doing for eight years. You know, whatever complication was going to happen, I would've seen it over the eight years or heard about it or had those patients sent up to me.
One of the things about being a referral center, where we are, is the -- a lot of challenging patients that others have operated on, so many of the issues that I would expect to see, I had seen already.
Q. So you thought you already knew what you

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were doing and you understood the material and the procedure enough to go forward?
A. Um-hmm.
Q. Did you look to peer review journals for data on the safety and efficacy of the TVT device?
A. Yes.
Q. What journals?
A. "Journal of Urology," the "Gold Journal," many of the urogynecology journals, abstracts presented at the AUA, updates to Campbell's "Urology," "Female Urology," Shlomo Raz's initial texts to learn about these procedures. A variety of different sources.
Q. In other words, you felt after looking at this data and having the experience of implanting mesh for eight years that the use of mesh and specifically Ethicon mesh in your hands was safe?
A. Yes.
Q. And you thought that, in part at least, based upon your own understanding and confidence and your skill level?
A. Yes. But also, you know, each year another paper would come out. More information would come out, case reports, other experiences, variations of

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how to do things. That shaped the knowledge that we have.
Q. Take a step back for a moment, though.
You know that there are thousands of women that have claimed injuries from the implant of vaginal mesh, right?
MS. ROBINSON: Object to form.
A. Many people have claimed that, yes.
Q. Would you, as you sit here today, agree with me that perhaps that mesh was too widely distributed to physicians and hospitals and put in too many women too fast by experienced -- or I'm sorry, by physicians who were not as experienced as you?
MS. ROBINSON: Object to form.
A. No.
Q. Why not?
A. I think that these physicians who implant, or whatever surgery they did, need to have a full understanding based on their skills and their training about what they're going to do, and they should be able to look at a product -- I mean, mesh is no different than Prolene sutures we've closed abdomens with and the same Prolene sutures we've done MMKs with or Burches. So they should

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know that based on their skills and training that this is just a different application of something that they've been doing for years. And their knowledge, their skills, that should be what moves forward to whether they're going to adopt something or not adopt something.
Q. That's not an answer to my question, though. My question was whether or not you believe that mesh -- let me back up for a second.
I think you and I agree, don't we, that physicians should be skilled in a procedure before they do that procedure, correct?
A. Physicians should be skilled in a procedure, yes.
Q. So we agree on that. What I'm asking you, though, is something different, which is, do you believe that mesh was too widely distributed and put in too many women too fast by inexperienced physicians, which is perhaps one of the reasons why we're seeing all these claims?
MS. ROBINSON: Object to form.
A. I don't think it had to do with the physicians' experience. I think that the physicians who were using mesh are very

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experienced. I don't think that they selected their patients carefully based on their skills and training. I think mesh is -- has done some amazing things for people. You're only talking about all the negative things. I don't have anything negative to say about it. Mesh has shaped the way we do surgery. Mesh has changed outcomes for people that never would have the outcomes that they do in a positive way.

Q. You mentioned that they made a mistake in the selection of their patients.

What do you mean by that?

A. The IFU is very clear. It's very clear. The first iteration of the IFU is very obvious. Mesh is used in the treatment of stress urinary incontinence. It's a treatment for stress urinary incontinence. It's not a prevention. It's not going to -- it's not going to treat something that's not there. It doesn't say it's a treatment for urge incontinence or mixed incontinence. It's a treatment for stress incontinence.

It's very clear. Many people who have implanted slings have not considered its true indication. And when you implant mesh in those

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people, they have -- they are more likely than less likely to have problems.

Q. Why?

MS. ROBINSON: Can we go off the record for a second?

MR. WALLACE: Yeah. Go ahead.

(Brief break.)

BY MR. WALLACE:

Q. Just answer the why, and then we'll take a break.

A. Just reorient me to the -- you know.

Q. My understanding of your testimony is that you believe, as a physician who's implanted mesh for a number of years, that one of the reasons why there are so many complications with mesh is because of patient selection, correct?

A. Yes.

Q. And that you believe, in part, that physicians, when they're doing patient selection, have sometimes implanted mesh in women that didn't need it?

A. That's correct.

Q. And including in women that may not be suffering from stress urinary incontinence but

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some other type of incontinence?

A. That's correct.

Q. And you believe that in seeing these complications, that that behavior by these physicians may be, in fact, a cause of those complications, right?

A. That's correct.

Q. And I said to you, why do you believe those complications come about?

A. You have to look at the revisions of mesh, the mesh removals to determine that. And when you look at, in our practice, in which we've removed probably close to 200 patients' mesh since we started counting them, paying attention to that, very few patients have had erosions. Most patients, when you look at the original indication, they had mixed incontinence, or they had urge incontinence, or the sling was placed prophylactically. And when you do that -- and that's well documented. When you do these procedures, or any stress incontinence procedure for that matter, it's more likely to fail. And then, of course, there's the patient comorbidities. Okay.

Q. Let's stop there before we go on to

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comorbidities.

You said it's well documented. What do you mean by that?

A. Well, the literature has described for years about who is more or less likely to do well when they have a sling placed. And it's well documented that patients with urge incontinence -- pure urge incontinence, that is -- patients with mixed incontinence, patients with multiple comorbidities, patients who were having multiple procedures done at the same time, like a hysterectomy and anterior repair and a sling, are more likely to do poorly as opposed to someone who just has a mesh placed or a sling placed for stress incontinence.

Q. Are there any peer review journals or articles that come to mind when you make that standpoint?

A. About which statement?

Q. The statement you just made about that literature or that it's well documented.

A. Yes.

Q. Which ones?

A. The Schimpf, the variety of Cochrane reviews, the reviews from the "Journal of Urology"

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as well. There are a variety of different reviews.
Q. Okay. Let's take a break.
(Brief break at 12:29 p.m.)
(Back on the record at 12:37 p.m.)
BY MR. WALLACE:
Q. You mentioned some of the other non-mesh procedures that you've done where you use sutures. Do you recall talking about that earlier today?
A. Yes.
Q. Are -- is using a mesh and doing, for example, a Burch procedure present the same risk?
A. Some are the same risk, but others are different.
Q. What are the differences?
A. Well, mesh is placed under the urethra, whereas Burch suspends it from above. So the complaints could be different. Burch patients may complain more of voiding dysfunction, difficulty with their stream, urgency, frequency, obstructive kind of symptoms. Yes, you can see that with TVT mesh-based pubovaginal slings, as well, but it's more urethral-related, more towards where the urethral meatus is.

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You can have more dyspareunia with vaginal-based procedures as opposed to Burch-based procedures, but that -- often they're combined with other procedures, so they may be having an anterior repair and a hysterectomy and an incontinence procedure, so you have to look at the whole picture of what they're having done as opposed to just the individual A versus B.
Q. But you would agree with me that there is a risk of greater dyspareunia with a vaginal mesh procedure?
A. Not necessarily. Again, it's the patient factor. So you operate on someone who's postmenopausal, you can have dyspareunia with either procedure, just because they're postmenopausal.
Q. But you can have greater dyspareunia with a vaginally-placed mesh product?
A. Not necessarily. I think that actually the risk can be pretty similar.
Q. And what science or data do you base that on?
A. Schimpf. It's to say that all procedures --
Q. Did you control, in Schimpf, when you looked

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at the table, did you control for all the different products that were examined?
A. You can't control for all of them. There's too many products. There's too many things. Because it's a meta-analysis, so what do you want to pull out? Which study you're going to pull out?
Q. Right. But you're relying on Schimpf, for example, to give me your answer --
A. Right.
Q. -- so I'm trying to figure out how specific you are. If you're just giving me a general opinion based upon a meta-analysis, that's fair. I just need to know that.
A. No. Most of the studies that were within Schimpf, when you're looking at a pubovaginal sling, for an example, there's only one of the studies that used mesh for its pubovaginal sling. All the other ones used autologous or cadaveric material. So that's a fair comparison. You don't have to pull anything out for that information, okay? And the other ones, you know, use Burch or MMK or other type of procedures. They're all pretty standard, how they're done, so there's really not a lot of factoring.

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Q. So in other words -- and let's suppose you're wrong, that your reading of Schimpf is wrong, that it isn't a straight comparison, in fact. Let's talk about autologous slings, for example.
Do you think, when you use the word "autologous" slings, are you saying that it only had to do with fascia?
MS. ROBINSON: Object to form.
A. Autologous, by definition, means self, so that means you got the fascia from that person.
Q. So when you're using the word "autologous" fascial slings in connection with the Schimpf article, you are not, for example, referring to Gore-Tex?
A. Right. One of the papers within Schimpf, of the ones that look at pubovaginal slings, that used -- I think it was Gore-Tex. I have to look specifically. I don't remember off the top of my head. But the other ones used either cadaveric or autologous fascia.
Q. Do you believe that the risks of using a suture that may erode present the same risks of a mesh that may erode?

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A. They both can be very significant, yes.
Q. Do they present the same risks?
A. I think they present similar risks. It depends on where the sutures are placed. You can do an MMK or a Burch and you can put a stitch right through the middle of the urethra and have a stone form on it or right through the bladder. And we've removed cases of people who have had Burches or MMKs and had erosion and had stones forming on their suture. So yeah, sutures that are inappropriately placed can certainly do that. Mesh that's inappropriately placed or a pubovaginal sling that's inappropriately placed can all have significant effects.
Q. You said that there are different risks with mesh. What are they?
A. I don't know that they're different -- well, some of the things relate to how they're implanted. You wouldn't expect someone who had an MMK versus a patient who had an obturator sling to have FIE pain because of, just inherent to how a needle has passed. So they may have a different subset of side effects based on the approach or what's been performed for them. Both can have voiding

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symptoms. Both can have pain. Both can have dyspareunia, but they may be for different reasons, or they may be for the same reason. You know, they may be -- like I said, they have atrophic vaginitis. They're postmenopausal. They're not on any estrogen. Or they have other risk factors, you know, age, parity, smoking, things like that.
Q. Are you aware of these mesh pain clinics that have come about in the last few years?
A. A mesh pain clinic?
Q. For example, there's a clinic in North Carolina that specializes in the removal of mesh now.
Are you familiar with that?
A. No. No.
Q. Are you familiar with the work that's going on at UCLA?
A. Which is what?
Q. That there are clinics that specialize in the removal of mesh?
A. No.
Q. Are you aware of any of the work that's being done in Atlanta in that area?

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A. No.
Q. You would agree with me that there is no center, nor was there ever any healthcare center, that specialized in the removal of sutures in the treatment of stress urinary incontinence, correct?
MS. ROBINSON: Objection to the form.
A. That has that written on their logo, you know, on their advertisement, on their billboard? I've never seen that, no.
Q. Putting aside whether or not somebody has it on a billboard, you would agree with me that that's never existed?
A. I've never seen it.
Q. Now, when a woman comes to you for treatment of stress urinary incontinence, do you typically examine her?
A. Yes.
Q. Do you do urodynamics testing?
A. Yes.
Q. And if the patient, for example, wants to bring in her spouse, is that okay to do?
A. During what, during urodynamics testing?
Q. During your pelvic exam, for example?
A. Oftentimes they're in the room behind the

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curtain, of course, but they can be present.
Q. You don't have a problem with that?
A. No.
Q. And you believe it might provide some comfort to the woman that's being examined, right?
MS. ROBINSON: Object to form.
A. That's up to her. I will ask each patient, after I do an examination of them or recommend a procedure for them, I will ask them, "Do I need to speak to your family?" And "Do you want me to speak to your family?" And if they want me to, then I will, and discuss what's going on.
Q. And the patient has a right to refuse treatment at any time?
A. Yes, they do.
Q. What is informed consent?
A. Informed consent is a process by which a physician will speak to a patient regarding a procedure or a test that they're going to have and discuss with them the risks, the benefits, things that may happen along the way, and have them sign a generic form to document that that discussion was had. That's only one part of informed consent. There's also things that are implied, that are

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assumed, and that are discussed about with patients that are not written on a form consent.
Q. If you had diagnosed a woman with SUI and have decided that surgical intervention is appropriate, what options do you give that woman?
A. I explain to them all of the options from nonsurgical treatments to surgical treatments.
Q. And what surgical options do you give her?
A. That depends on what their situation is. If someone has sphincteric incontinence, they could be offered injectable treatment. If they have hypermobility, they can be offered a sling via autologous, via -- we're talking pubovaginal. They can be offered a pubovaginal sling via autologous or cadaveric fascia. They can be offered a suburethral sling via mesh, and then now, for the most part, I do them by the obturator approach. Or they can be offered observation.
Q. So you offer all those options to someone that's been treated or diagnosed with stress urinary incontinence?
A. Yes.
Q. And you would agree with me that some of those surgical options, like Burch and non-mesh

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sling procedures, are perfectly appropriate, within the standard of care?
A. They can be offered to the patient, sure.
Q. When you tell a woman that she can receive a mesh polypropylene sling, what are you telling her?
A. Explain to them the details of the procedure. Explain to them the risks of the procedure, certainly, obvious things like bleeding, injury to other structures along the way, including the bladder. I discuss with them the risks of erosion and extrusion. I discuss with them the risks of pain, and I discuss with them the importance of following up with me on an annual basis because they may develop problems not only initially, but years down the road.
Q. And how long have you been telling that to your patients?
A. Since I started here.
Q. 2001?
A. Yes.
Q. So it's your testimony that since 2004 you have told your patients that were deciding whether or not to receive a mesh-based polypropylene sling those things you just described?

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MS. ROBINSON: Object to form.
A. For any patient who I'm treating for stress incontinence, that they should come back on an annual basis, but in particular, people who've had surgery. If someone is treated with observation and they want to come back, that's fine. I give them an appointment. But for any patient that has any surgical procedure, I want to follow them annually.
Q. Do you have a standard informed consent form that you ask patients to read?
A. I have a standard informed consent form. We use the hospital informed consent form. But I read to them an additional statement or statements that becomes a part of their medical record, about slings, the position statement on slings, the complications, and the problems that can happen with them. And I do that for every procedure.
Q. And how long have you been doing that?
A. I've been doing that since 2010.
Q. So you'd agree with me that prior to 2010, you weren't reading that additional statement?
A. No. I was telling them all these things, but, unfortunately, we're in a world now where you

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need to do more than that.
Q. What -- as opposed to unfortunate, you accused me of only looking at the negative things earlier. Isn't it more positive to look at it in a way that you're giving better informed consent now based upon the circumstances?
MS. ROBINSON: Objection.
A. No. I think I'm giving them fine informed consent. When I have a patient come in to me who's referred from -- just referred for a consideration and says that "I need you to take out my mesh because it's been recalled," you know, there's a problem with interpretation of the world. And I have patients that come in and say, "Well, I don't want mesh because it's bad for you."
We have a problem. So we need to document better because patients will turn around -- and, you know, they may be contacted, patients are cold-called now. My patients have been cold-called about a sling, and, you know, they want to know if everything's okay. I certainly didn't call them, nor would I call them, but someone called them.
So, you know, now, unfortunately, we're in a society where I know this is a standard procedure

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that's done wonderfully for my patients, but I need to document everything that goes on because these are now big issues.
Q. Do you -- in documenting, do you keep a list of all your patients that you've seen and put mesh in over the years?
A. Do I keep a separate list of them? I have access to that, yes. I can look and see who's followed up with me, our EMR list.
Q. How many -- what percentage of your patients have failed to follow up with you?
A. I don't know. I haven't looked at that and summed that out.
Q. Well, so, why don't you look at page 4 of Exhibit 3. Is that the Hendrix report?
And I'm sorry, Doctor, let's make sure we're looking at the right thing.
A. The Hendrix report.
Q. Okay. Thank you.
So is it fair to say that your testimony is that you have not kept an actual log of patient satisfaction over the last 16 years since you've been in West Virginia treating women for stress urinary incontinence?

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A. You asked a whole lot of things. First, it was a patient log. Now, you asked about a patient satisfaction log. I mean, those are two different things.
Q. Well, answer the question that I just asked, then.
A. I don't know. I don't know what you're asking.
Q. Well, you say you don't keep a separate log relating to your patients, right?
A. No. I didn't say that. I said I only keep a separate log of patients who've had implants. I know all the patients that we see because our EMR can follow those patients. I can look at the diagnosis code, I can look at a procedure code, and I can acquire information like that. But I have looked at our long-term results of patients -- I have not published it -- and slings that I have done 15 years ago of the patients who are still in our practice. I can tell how they're doing.
Q. But you can't sit here today and tell me how many of those patients that you've put slings in over the last 16 years are unsatisfied?
A. I would say that very few of them are

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unsatisfied.
Q. Where's your proof?
A. I have a very good track record of -- I'm the only subspecialist who does female pelvic medicine in the state of West Virginia. So if they're not going to come and follow with me, they're going to go to Cleveland or Pittsburgh or to another major center. So I'm the only sub-boarded specialist in my area. I expect people to follow with me. I'm very direct about their need to follow on an annual basis, and when they don't follow, then, you know, I can't be held -- you know, I can't expect, you know, them to come when I tell them to and they don't.
But it's very strong. I have people that -- from back 15 years ago that still follow up because they know it's important to do and they know when they have problems to do.
Q. And I'm pleased to hear that you impress that upon them. My questions, though, are more basic.
As much as you might ask somebody to follow up with you, a woman, if she is unsatisfied with you, may choose not to, right?

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A. They might, but they probably won't. They'll -- initially, they come to you, so it's your opportunity, on the one shot that they're unsatisfied, to figure out why. So most people will come back when they're unsatisfied. You'll get another shot since you did their surgery.
Q. So you disagree with literature suggesting that 50 percent of women who are unsatisfied don't follow up with the implanting physician?
A. I think that's -- I know what paper you're referring to. But there's others that show that they do follow up with their implanting physician.
Q. And in your experience, just based upon your review of your EMR system, you think that there's excellent follow-up at your facility?
A. I do think so, yes.
Q. But you can't give me a number or percentage today of the women that have failed to follow-up with you, right?
A. I can't.
Q. So in other words, when you see on page 4 of the general TVT report that you've had excellent long-term patient satisfaction over 14 years, you can't provide me with any statistical evidence of

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that, as you sit here today?
A. No.
Q. And you, because we're at your deposition, and you have brought documents, you haven't provided anything to us today that would allow us to make those calculations to verify the truth of this statement that I just read from page 4, right?
A. Right. The statement is a true statement. But to verify that statement, actually, would require a study. It would require an IRB for me to look at my patients and to see who's satisfied and not satisfied to report that to you.
Q. Well, you would agree with me, though, that we can't let anyone just say it's so just because I'm a great physician and I say it's so, right? Otherwise, anybody could come in the room and say whatever the heck they want, right?
A. Right.
Q. So do you agree with me you can't just come in the room and say it's so just because I say it's so?
MS. ROBINSON: Object to form.
A. We have to assume that people are being truthful in what they say.

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Q. But I have the right to cross-examine you and test the veracity of your statements, right?
A. Sure.
Q. And if I can't do that -- or I'm sorry, I can't do that with this statement except just take your word for it?
A. That's correct.
Q. I have no independent data to look to or test?
A. That's correct.
Q. You said earlier you read the instructions for use?
A. Um-hmm.
Q. And do you read the instructions for use every time you do a surgery?
A. Initially, sure.
Q. When's the last time you put in a TVT?
A. Last week.
Q. Did you read the instructions for use before you did it?
A. Not before that procedure. I've looked at it in the past.
Q. When's the last time you looked at the TVT instructions for use?

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A. Within the last year.
Q. And you would agree with me that the instructions for use are a primary way in which a company can describe the procedure and give you the contraindications and the warnings, right?
MS. ROBINSON: Object to form.
A. They can do that based upon information that they know, whether they think it's important to be included in there.
Q. Right. So if there are certain risks that may come with the procedure, it should be in the instructions for use, right?
A. If it's unique to that procedure, then it should be included in it.
Q. You would agree with me that the implant of a TVT can cause retropubic bleeding?
A. The implant of a traditional TVT?
Q. Yes.
A. Yes, it could.
Q. And it could cause erosion?
A. Yes, it could.
Q. It can cause extrusion?
A. Yes, it could.
Q. Can cause fistula formation?

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A. Mm-hmm.
Q. Chronic inflammation?
A. I don't know about chronic inflammation.
Q. Why not?
A. Because it would depend on the setting of when it is. I mean, to have something that's chronically inflamed would most likely be extruded, so some of the things are going to go with other things that you've mentioned.
Q. Well, my question is, though, an implant of a TVT can cause chronic inflammation, right?
A. It would depend on the situation. It would depend on the clinical presentation of the patient and whether that mesh were removed and whether it was resolved of their symptoms thereafter, and it would involve maybe looking at the pathology of that as well.
Q. In other words, it can?
A. It may. It depends on the circumstance. Not in all circumstances, but it may.
Q. And the chronic pain can be associated with the implant of a TVT?
A. It can be associated with any pelvic floor surgery.

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Q. But I'm asking a question specific to the TVT, so I'd like to limit our question and answer to that. So let me ask it again.
The implant of a TVT can be associated with chronic pain, correct?
A. It can.
Q. And you would agree with me that there's a difference between postoperative pain and chronic pain?
A. Yes.
Q. And you would agree with me that the use of the word "transitory" has to do with what would typically be associated with postoperative pain, right?
A. Transitory would refer to postoperative pain.
Q. Transitory does not refer to chronic, long-term pain?
A. No.
Q. And what is postoperative pain?
A. It's pain that occurs postoperatively.
Q. And it usually disappears within a few days or sometimes a couple of weeks?
MS. ROBINSON: Object to form.

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A. It may, it may not.
Q. Well, when it goes on for a period of sustained time, that interferes with the patient's quality of life well after the surgery, that's chronic pain, right?
A. It could be, yes.
Q. Well, do you have another definition for "chronic pain"?
A. It could be, as you said, pain that affects quality of life, pain that affects their activities in some way.
Q. And that can happen many years after the implant of the medical device, correct?
A. Yes. But usually not. Usually, the pain is something that starts postoperatively and continues.
Q. But it can be different from the pain that was postoperative, right?
A. It usually is persistent.
Q. Well, let's talk about the case of the TVT. You're aware of women that have been pain-free for years and then suddenly years later they develop chronic pain that they associate with the TVT implant --

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MS. ROBINSON: Object to form.
Q. -- correct?
A. They -- the patient may think that.
Q. Would you agree that there are few studies, if any, that track chronic long-term complications associated with the TVT?
A. No. There's good data looking at long-term erosions and long-term -- and most people with erosions or extrusions are going to be the ones who have pain. Very few people who have had a carefully-implanted device will have long-term pain.
Q. Name one article that tracks chronic long-term pain associated with the TVT.
A. The original work by Olmstead, in his 90 patients, he only had a single patient with issues. Look at the extrusion rates from the Cochrane review. And I'd have to look for specific names of other sources. But there are a variety of others that looked at erosions and extrusions and most of which would have pain.
Q. Okay. But I didn't ask about erosions or extrusions. I asked you to name one study that tracked chronic long-term pain associated with the

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TVT.
A. I can't name one.
MS. ROBINSON: Just to be fair, you're not asking him to look at his records, reports, or anything he has sitting in front of him, right?
MR. WALLACE: He can look at anything he wants.
MS. ROBINSON: Well, if he can look at anything he wants, you might want to take a few seconds and look at what he's got.
MR. WALLACE: And just for the record, we're letting Dr. Zaslau review his materials in an attempt to answer the question as to whether or not there's one study that tracks long-term chronic pain with the TVT.
THE WITNESS: I can't think of or see one that specifically refers to that for the long-term.
MS. ROBINSON: You also have your studies in front of you as well.
THE WITNESS: Right.
MS. ROBINSON: And you've spent less

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than a minute here looking through your report.
MR. WALLACE: You get to ask him questions later.
THE WITNESS: In the Tomaselli paper, just looking at the long-term pain complications of which the risks appear to be very low, but can occur with minimally invasive slings.
Q. What's the citation of that, please?
A. Tomaselli 2014.
Q. How far out is that study?
A. That is October 2014.
Q. No. I mean, how long did they follow the patients for?
A. It's searched up to -- it's another meta-analysis, but the review is up through June of 2014. Google databases up through June of 2014. Also, the Unger paper from April of 2015 looked at vaginal pain and groin pain and found a risk of 8 percent for vaginal pain and groin pain of 3.4 percent.
Q. How long did they follow those patients?
A. These are patients from June of 2003 to

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December of 2013, and the follow-up was -- the median time is about 18 months.
Q. So the median follow-up is about a year and a half?
A. Yes.
Q. What qualifies as a long-term study?
A. We like to see more than five years of data.
Q. That doesn't qualify as a long-term study, does it?
A. No.
Q. So in other words, that article, though you have said it follows some back pain and groin pain, it doesn't qualify as a long-term study following chronic pain associated with the TVT even under your definition, right?
A. Um-hmm.
Q. When you say "um-hmm," you mean you agree with me?
A. Yes.
Q. Thank you. When you counsel a patient that is about to be implanted with a TVT, do you tell her that she may have persistent pain with intercourse?
A. Yes.

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Q. And she knows that that pain may, in fact, if things don't go as planned, could last the rest of her life?
A. It can be long-term.
Q. Can you yourself remove all of the mesh from a woman that has had a TVT implanted in her?
A. I wouldn't want to remove all of it.
Q. That's not what I'm asking. Can you?
A. Depends when it was implanted.
Q. What if it's been implanted for more than six months?
A. It's tougher.
Q. What do you mean by that?
A. It will integrate within normal tissues.
Q. Have you ever removed the entirety of a TVT from a woman?
A. No.
Q. And that would be a very morbid procedure, wouldn't it?
A. No. It would be a very unnecessary procedure.
Q. Let's -- not disputing "necessary" right now.
You don't think it would be morbid at all?

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A. I didn't say it wouldn't be morbid. I said it wouldn't be necessary.
Q. Putting aside whether or not you believe it's necessary as a physician, would removal of the entire TVT be a morbid procedure?
A. It depends how it was placed.
Q. Could it be more morbid than an autologous sling, would you call morbid?
A. It could be as morbid as an autologous sling. Autologous slings can be very difficult to remove.
Q. I'm talking about the -- removing the fascia from the abdomen. Do you follow me?
A. No.
Q. Let me back up, because I took a step that perhaps we can deal with.
My -- let's go back to my simple question. Even though you've never removed the entirety of a TVT from a woman and disagree as to whether or not that would be necessary, would you agree with me that it is a procedure that would require significant dissection?
A. It could require significant dissection.
Q. Of what?

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A. Of the tissue where it was placed.
Q. Using what tools?
A. Standard surgical equipment.
Q. Like Metzenbaum scissors, for example?
A. Right.
Q. So, in other words, you literally have to try to cut it out, but when you're cutting it out, you're taking tissue with it?
A. Well, it's hard to dissect because it's grown into the tissues.
Q. So you're taking tissue with it when you're using these Metzenbaum scissors, right?
MS. ROBINSON: Object to form. Asked and answered.
A. You're taking tissue with it.
Q. And that's undesirable?
A. It may or may not be desirable. It depends on what the patient's complaining of or what the problem is.
Q. Well, you'll agree with me that cutting into a woman like that is not something that you would do lightly?
A. Cutting in to do what, to remove an implant?
Q. Correct.

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A. It's a very straightforward thing when it's done for the right reasons, to remove what mesh needs to be removed.
Q. Have you ever seen a woman erode in one area of the vaginal wall and you remove that mesh, and then she has an erosion in another place later?
A. Sure. You can have that, yes.
Q. So when you just gave your answer that you only remove what's necessary, how do you know that?
A. You have to follow them and see. It depends, again, on why you're removing the mesh. Why are we removing this person's mesh that you're talking about? Is it eroded? Is it extruded? Is it pain? What are we removing it for?
Q. What do you remove mesh for?
A. All the reasons that I just said to you. So someone's mesh is extruded, the easiest thing to do is to remove the extruded portion of it and follow them and see.
Q. Have you always -- let me -- I'm sorry. Are you done with your answer?
A. No.
Q. Go right ahead.
A. So that doesn't mean they can't have

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another area of extrusion later, for other reasons, such as being postmenopausal, being a smoker, having atrophy. So they can have an erosion at another time, from another area that wasn't a problem before then, but then became a problem years later.
Q. Do you tell women that they may have to have multiple -- or that they may have multiple erosions and multiple surgeries?
A. I tell people they need to follow up annually so we can assess them and see what they have that's going on.
Q. But that doesn't answer my question. Do you tell women that they may have multiple erosions and multiple surgeries?
A. It does answer your question, because you have to see what they have that's going on to know what to do for them. That's implied, is that they had surgery, they could have problems that require additional surgery or surgeries.
Q. Again, I'm going to make my question even more simple: Do you when you're consenting a woman that's about to be implanted with polypropylene mesh tell her that she may have

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multiple erosions that require multiple surgeries, yes or no?
A. Yes. I tell them that they will require -- that they can require multiple procedures down the road.
Q. Do you tell them that they may have multiple erosions?
A. I don't tell them that they'd have multiple erosions. I tell them that they can have erosion or erosions.
Q. Do you tell them that they may be on chronic pain medication for the rest of their lives?
A. No. I tell them that they may have chronic pain, and that pain -- they may have pain, and that pain may be acute or it may persist and be chronic, and they may require other therapies for that.
Q. You agree that chronic pain is challenging to treat?
A. Yes.
Q. And you would agree with me that improving someone's baseline even 30 percent is sometimes a good outcome?
A. That's the goal of giving people narcotics, to improve them by 30 percent. That's the

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definition of pain improvement.
Q. And you would agree with me that they're still missing 70 percent improvement even with narcotics?
A. It depends on the other situation. There's multiple reasons why a person can have pain.
Q. I'm just trying to get you to agree with some simple math.
A. I'm not understanding where you're getting the simple math from.
Q. You're improving someone's -- your understanding of the reason why pain medications are given is to improve someone's baseline of pain 30 percent, and if that happens, that is a good outcome, correct?
MS. ROBINSON: Object to form. Misstates his testimony.
A. That is the goal. We'd like to improve them more than 30 percent.
Q. So if they only improve 30 percent, they still have 70 percent to go?
A. It may not be possible to obtain that.
Q. And you have seen women that are being treated for chronic pain that is associated with

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mesh that use tramadol?
A. I've seen people use tramadol, yes.
Q. And do you know that tramadol is used by NFL players to treat their pain after games?
A. I don't know what NFL players use to treat their pain.
Q. While we're sitting here in Morgantown, do you know whether or not the Mountaineers use -- players use tramadol after games?
A. I don't know that.
Q. Would it surprise you to learn that that's a commonly prescribed pain medication that's used for those players that undergo those collisions?
MS. ROBINSON: Object to form.
A. It wouldn't surprise me, and it wouldn't concern me. It doesn't relate to me.
Q. But you would believe that there are big side effects associated with chronic pain medication?
A. There are.
Q. And that's something you want to avoid, if at all possible, right?
A. You'd like to, yeah.
Q. So for example, you're aware that Neurontin

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is another medication that's used to treat chronic pain?
A. Yes, it is.
Q. In women that have mesh implants, right?
A. These are all things that have been used, but most people that I come across don't have that and are easily fixed of their chronic pain.
Q. I understand that you're a successful doctor, but you would agree with me that you've also seen women that are being treated with these drugs?
A. Initially, before they come to me, yes.
Q. But you're not saying that it's inappropriate to try to use these things to manage chronic pain or anything?
A. Yeah. I think you need to find out why they have chronic pain. You need to figure out why -- treating pain only gets rid of the pain. We need to know what the source of the pain is.
Q. You yourself have used Elavil?
A. I have.
Q. There are side effects associated with that?
A. I prescribe Elavil, yes, if that's what you mean, yes.

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Q. Have you ever prescribed it to a woman with a mesh implant?
A. I have not.
Q. And you've seen women go back to Neurontin, for example. That's a medication that has some side effects, right?
A. Sure. These all do. But I don't routinely give any of these medicines to these people with chronic mesh pain.
Q. Are you saying that a doctor that tries to do that for a patient that is suffering pain, chronic pain, is not following the standard of care?
A. That's not a standard-of-care issue. It's a judgment call. Their judgment is they want to treat pain with pain medicines. Another way of treating their pain would be to go to what the source might be, to a good physical exam, urodynamics, if necessary, and see if that pain is reproducible, and then there are certainly surgical options that can be performed.
Q. You believe that depression can come about as a result of chronic pain, right?
A. It can go either way. You can have pain

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that causes depression and depression that causes pain.
Q. And you've described that as a vicious cycle?
A. Yes.
Q. Do you tell your clients that they may have -- that may happen to them as a result of a TVT implant?
A. No. Because they shouldn't have chronic pain from this. I tell them that they certainly may have pain, but again, you're following them regularly, so you'll know if something has changed in them in their postoperative visits.
Q. Would you agree with me that once somebody starts taking medicine like that, we've described, that there are some things that happen to them medically that you just cannot explain?
A. I don't know what you mean by that.
Q. Well, that's your testimony before. So that's what you've said before.
A. Well, I don't know the context that it was said in. What was the question? What was the situation?
Q. Let me -- I can go there, if we need to, but

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let me try to short-circuit it, given our limited time frame.
You've said before once people -- I'll take whether or not you've said it before out of it. I'll just ask you more directly: Once people start taking chronic -- I'm sorry, pain medication for long-term chronic pain, there are sometimes things that happen to them medically that are not readily explainable?
MS. ROBINSON: Object to form.
A. Yeah. Like I said, I don't know the context of where that's coming from.
Q. Do you recall saying in the Edwards deposition that with medication there can be idiosyncratic effects that happen that cannot be explained?
A. Yes.
Q. Do you know why you said that?
A. People can have -- idiosyncratic in medicine implies that if something has happened to them that is unexplainable, maybe they have a change in their vision, maybe they have a new onset of muscle pain in muscles that they have never had pain in, so they can have responses or reactions that are not

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explained.
Q. And we want to avoid synthetic things like medicine when we can?
A. Synthetic things?
Q. Well, medicine -- the medicine that we've been talking about is manmade.
A. Right.
Q. And we want to avoid foreign bodies when we can?
A. I don't know about that.
Q. Why not?
A. What do you mean by "foreign bodies"?
Q. Well, you know that the body itself, when it's implanted with anything or we take a drug, there's a foreign body response?
A. The same thing happens when you implant a piece of your own body into it.
Q. So you think that synthetic is preferable to a nonsynthetic?
A. In what context? You talked to me before about medicines, like Elavil and tramadol, and now you're talking about something synthetic. So I don't know what you mean by synthetic as a medicine, as opposed to not taking a medicine, or

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synthetic in another context? I don't know what you're asking me.
Q. Would you agree with me that it's more desirable to try to avoid taking medicines like those we've just described, for example, Neurontin, Elavil, perhaps even oxycodone, right?
A. Yes.
Q. Those are all manmade products?
A. Um-hmm.
Q. You said earlier that you removed -- if I understood you correctly, approximately 200 slings since you've been counting?
A. Yes.
Q. I thought you said in Edwards -- and maybe the numbers have changed since then -- that it was about 75?
A. We're close to that. My gynecology colleague has -- we've done some together, so I've looked at the patients that he's treated since, you know, we worked together on some cases. I'm involved in his, and he's involved in mine. So within the bulk of us, we're probably close to 200.
Q. How many of those are slings compared to prolapses.

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A. Most of them are slings. Very few of them are prolapse.
Q. Why is that?
A. Slings more commonly performed in terms of a procedure than a Prolift -- a prolapse case.
Q. How many of those 200 were your implants?
A. Two of them were, maybe three or so, but really, less than a handful.
Q. How do you know that?
A. Because they were the only cases I did. They had surgery somewhere else.
Q. As you sit here -- and I'm not going to ask you the names -- but as you sit here, do you know the names of the individuals that had to have their sling removed --
A. No.
Q. -- that were your patients?
A. No.
Q. So why do you come up with the two or three?
A. Because it's a very, very small number of people over the years that I had to remove their slings.
Q. In other words, so approximately 197 or 198

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of the 200 are not implants of yours?
A. That's right.
Q. When you remove those slings, do you report them as adverse events?
A. No.
Q. Why not?
A. Because very few of them were extrusions, so there's no reason to report that.
Q. The few that were extrusions, did you report those as adverse events?
A. No. Because those are expected complications of the procedure. The other ones were removed either because patients wanted them removed, or they had obstructive voiding symptoms, or wanted some relief of whatever's going on with them, be it dyspareunia or such.
Q. Well, when someone has dyspareunia and has to have a mesh removed, that's an adverse outcome of a procedure, correct?
A. No.
Q. You don't think so?
A. No. It is an expected --
Q. Have you asked any of those women whether they think that's a good thing or a bad thing?

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A. Well, this is an expected complication of pelvic floor surgery. It's something that should have been discussed with them by any person who does pelvic floor surgery.
Q. So if the rates of complications -- you realize -- let me back up for a second.
You realize that there are many physicians, in fact, lots of physicians besides you that disagree with your definition of an "adverse event" and report removals?
MS. ROBINSON: Object to form.
Q. Right?
A. People have different practice ways.
Q. Well, you'll agree with me that there are many physicians because --
A. I don't know who reports what and how -- and what the individual practices are, of who reports things.
Q. So the only reporting that should be done should be in connection with the study is your opinion?
A. I think it should be done in connection with a study, yes. Unless there's an egregious issue that had gone on with a procedure that was

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untoward and unexpected in any imagination of how it should be performed.
Q. You used the word "untoward" in prior testimony as well.
What do you mean by that?
A. If you put a TVT trocar in and you perforate someone's stomach, you should be nowhere near someone to be able to do that, where you perforate an organ that's nowhere in your surgical field.
Q. Wouldn't it be important for the public and/or physicians and ultimately patients to know that the rates of complications are high?
A. Who said they were high?
Q. Or low?
A. Well, we know that they're low. We've seen that through the literature.
Q. So the sole basis, besides what's in your hands, meaning your own experience, that the complications are low -- actually, I'm going to ask the question a better way.
You rely on the literature and your own experience to conclude that the complications associated with the TVT are low, correct?

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A. I also rely on presentations of the AUA, Webinars from other societies, position statements by societies.
Q. So if physicians believe that you should be reporting removals for dyspareunia as an adverse event, you would disagree with them?
A. I didn't say I would disagree with them. If there's a national standard that has been accepted and put in place by a specialty board, then we all should follow the same standards.
Q. Do you?
A. I do not report them.
Q. Do you follow the standards?
A. Yes.
Q. You're certain?
A. I follow the standards.
Q. Has it been your practice in all 200 or so of those surgeries to send what you've removed to pathology?
A. Yes.
Q. And if I understand what you've said before about that, you see localized chronic inflammation when you get it back?
A. Yeah. Well, the vast majority have

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localized chronic inflammation.
Q. And you see some fibrotic bridging?
A. We see some fibrosis.
Q. What's the difference?
A. Fibrosis is a scar formation as a result of fibroblast infiltration of tissue. Breaching may be such that the pore size of the mesh will shrink in a way to create more of a bridge of scar.
Q. And you've seen that in some of these pathology samples that -- where you've removed the mesh, right?
A. I haven't seen that, no.
Q. You've seen fibrosis, though?
A. I've seen fibrosis.
Q. And the scarring, you believe, that's undesirable?
A. No. Scarring is a part of healing. Fibrosis is a part of healing.
Q. Well, you have said before, though, that with respect to tensioning, for example, that getting scarring as a result of too much tension is undesirable and can cause pain, right?
A. Yes.
Q. So you agree with the statement I just made?

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A. That undue tensioning can be associated with pain, yes.
Q. And that's because of scarring?
A. It may. It may also be other causes as well.
Q. When you look at these pathological examples, do you see evidence of foreign bodies?
A. Some -- what do you mean by "foreign body"? I mean, mesh is a foreign body.
Q. What else do you see?
A. It depends what the specimen is looked for. Oftentimes I'll see evidence of chronic inflammation, multinucleated giant cells, areas of fibroblast infiltration. Very few, if any, had any acute inflammatory process, neutrophils and such. And some, depending upon the pathologist, may show the presence of polarizing tissue or polarizing fibers.
Q. And you've seen tissue that is wound up in the mesh?
A. I've seen tissue that's incorporated in the mesh.
Q. You don't test for degradation?
A. Degradation, why?
Q. No. I just asked, do you test for

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degradation?
A. We don't specifically test for it.
Q. Have you ever had to tug on the mesh to get it out when you're doing removal?
A. I'm trying to dissect it to get down to where you think it is. Oftentimes there's a lot of scar depending upon where it was placed and who placed it. And we try not to tug on it. We try to dissect it as free and as easily as we can.
Q. Would you be surprised to know that even some urologists that are even more experienced than you have had to literally wrap their hands around the a piece of mesh and tug on it to get the rest of it out?
MS. ROBINSON: Object to form.
A. I would hope they wouldn't do that. There's no reason to do that. I wouldn't be surprised that they would do that, but it's not necessary.
Q. Some have done that, right?
A. I haven't heard of anyone who has, but since you say, I'm sure somebody has, and there's no reason for them to do it.
Q. Can you guarantee a woman that you can get all of her mesh out?

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A. No. And there's no reason to.
Q. Is it foreseeable that someone with a TVT mesh in them may need to have other surgeries in that area?
A. Sure.
Q. And, in fact, a woman may present to you as healthy and a perfect candidate for the TVT on April 1st of 2016, but by December 31st of 2016, she may be in poor health and may need surgery in the area in which that TVT was implanted?
A. I don't understand what you're referring to. They shouldn't need surgery there. We assume they've had a good exam, they have no other prolapse and no other findings, that they shouldn't need any other surgery.
Q. But it's perfectly possible that they might?
A. I'd have to know the situation. I don't know what we would possibly be going in there for.
Q. Do you use the TVT mechanical-cut or the TVT laser-cut mesh?
A. I use them both.
Q. Do you make a specific request for one over the other?
A. No.

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Q. And how do you know whether or not you're using a mechanical-cut versus a laser-cut mesh?
A. Well, I actually didn't know the difference until these litigation cases have brought this into the world. I've had no issues with -- in knowing the difference in either of them, nor do I think it has any clinical relevance.
Q. Well, do you disagree with Ethicon?
A. I don't see any difference in either of the two.
Q. Well, I'm asking you: Do you disagree with Ethicon?
MS. ROBINSON: Object to form.
A. With regard to what?
Q. Well, Ethicon felt that there was a clinical need for a laser-cut mesh, didn't it?
MS. ROBINSON: Object to form. If you know the answer to it.
A. I don't know that they -- I know that they have -- that information had been given to them, that, you know, maybe this should be considered, and obviously they did. But it wouldn't have mattered to me. I've not seen a difference or a need for it.

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Q. Okay. So you personally have not seen a different need for it, but you would agree with me that Ethicon received information, and as a result of receiving that information, it concluded that there was a clinical need for laser-cut mesh?
MS. ROBINSON: Object to form.
A. I don't know that there's a true clinical need. It doesn't make sense to me that --
Q. So in other words, there's no need for laser-cut mesh?
A. I don't think there's a need for it.
Q. So Ethicon is just making this up?
A. I didn't say they're making it up. I just said that I don't think there's a need for it. I haven't seen a difference in my patients that I can say, "Wow, I'm so happy that I used laser-cut mesh and not mechanically-cut mesh."
Q. Well, you would expect Ethicon to make its decisions based upon good medicine and science, right?
A. I would expect them to have good reason for the things that they do.
Q. So if they concluded that there was a clinical reason to come up with a TVT laser cut,

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you'd have to trust their judgment?
A. I would hope they would make good decisions.
Q. And do you know how many TVT mechanical-cut meshes you've implanted in your career?
A. Well, the changeover is about 2007 or 2008, so I don't know, 200 or so.
Q. Do you know how many TVT laser-cut you've implanted in your career?
A. In 2007-2008 to the present, probably 150 or so.
Q. As you sit here today, do you believe that laser-cut is the only type of TVT mesh that is offered, or is mechanical-cut still available?
A. No. I think that mechanical is still available.
Q. Have you ever been told by Ethicon that there are different risk profiles for the TVT mechanically-cut versus the TVT laser-cut?
A. What do you mean by "risk profile"?
Q. That the TVT mechanical-cut comes with different risks than the TVT laser-cut?
A. Risks of what?
Q. Risks to the patient.
A. No.

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Q. Has anyone ever told you that the TVT mechanical-cut mesh can rope?
A. Yes, I've heard that.
Q. From who?
A. From review of the literature.
Q. Have you ever observed that?
A. Yes.
Q. When?
A. When we do different experiments with the mesh ex vivo. So when we pull on the mesh by itself, be it mechanically-cut or laser-cut, it'll rip and tear, and it won't regain its normal form. And the pore size will certainly be distorted. But, interestingly, when we do the same thing with the plastic sheath over it, we can't move the mesh despite how hard we pull. We've actually even looked with an operative telescope at patients that we finished doing the TVT on to see if there is any evidence of fiber loss or any change in what I think the mesh should look like, and I've never seen any.
Q. Have you published the results of that testing?
A. We did not.

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Q. Where's the data to back up that claim?
A. It's personal experience and just bedside teaching.
Q. So I just have to take your word for it?
A. That's correct.
Q. There's no data that I can look at or cross examine to test the veracity of that statement?
A. To test the veracity of what I just said about pulling them and rip -- and pulling them apart? Well, certainly, you can look at what your own experts and the pictures that they have provided about stretching mesh ex vivo and you'd see particle movement and flaking of that, certainly.
Q. I'm talking about what you did, though.
A. I don't know that anyone else has done that. But --
Q. So it's you and your partners looking right after a surgery before there's been mesh ingrowth?
A. Right.
Q. Have you ever been told that TVT mesh can curl?
A. I've been told that, yes.

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Q. By whom?
A. By review of the literature.
Q. And have you ever been told that the TVT mechanical-cut mesh can release -- that there can be particle loss associated with the mechanical-cut mesh?
A. I've read that.
Q. And my understanding is you don't believe that has clinical significance?
A. I don't think it does.
Q. You would agree with me, though, that it's well-established in the scientific and medical literature that particles that are of a foreign body cause a foreign body response, correct?
A. When you say "foreign body," you're referring to mesh as a foreign body, right?
Q. Correct.
A. So you're not referring to autologous slings. That's a foreign body, too. It has no blood supply, so they can cause a foreign body reaction, too.
Q. You're not answering my question. I'm not talking about autologous slings right now. I'm talking about particle loss associated with the

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mechanical-cut mesh. Let's stick to that for a moment, just to finish this line of questioning.
You would agree with me that you've seen reports of that in the literature?
A. Yes.
Q. And you would agree with me, given your hefty reliance list, that you've also seen some Ethicon documents on that?
A. Yes.
Q. And you still conclude, even after reviewing those documents and that literature, that there is no clinical relevance to that issue?
A. That's correct.
Q. And you would agree with me that the particle loss that Ethicon describes, as well as the literature, is from the TVT mesh itself --
MS. ROBINSON: Object to the form.
Q. -- which is a foreign body?
A. That the particle loss is from the TVT?
Q. Correct. It's pretty well-accepted, right?
A. Yeah.
Q. I'm not trying to start a disagreement between us. I'm just trying to get through this.
And you would agree with me that your

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opinion differs from other physicians about the clinical relevance of particle loss?
A. It differs.
Q. In what way?
A. Well, experts believe that this can be a source of pain for patients, and other associated symptoms that are supposedly debilitating and lifelong and very problematic.
Q. And you would agree with me that Ethicon itself concluded, at least in part, that the clinical basis for coming up with the laser-cut mesh was the particle loss associated with the mechanical-cut mesh?
MS. ROBINSON: Object to form.
A. That may have been a consideration for them, but --
Q. In fact, you've seen documents that suggest that?
A. Yeah.
Q. And your reliance list. Even you've seen Ethicon documents that suggest that's a clinical basis for changing the laser-cut mesh, right?
A. It very well could be.
Q. I mean, you're not going to disagree with a

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document that you've seen that says that, right?
MS. ROBINSON: Object to form. Asked and answered 100 times.
Q. Correct?
A. I have no other comments.
MR. WALLACE: Let's take a five-minute break.
(Brief break at 1:41 p.m.)
(Back on at 1:44 p.m.)
BY MR. WALLACE:
Q. These Ethicon documents that we've been discussing for the last several minutes about particle loss and the clinical implications of that, did Ethicon share those with you prior to your being hired as an expert?
A. No.
Q. Were any internal Ethicon documents ever shared with you prior to you being hired as an expert?
A. No.
Q. So the Ethicon documents that you had access to would include anything that was provided to you in the instructions for use and anything that might have been given to you by a sales representative,

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right?
A. Yes.
Q. And as I understand it, given your academic setting or at least your setup now at the university, sales representatives don't have unfettered access, do they? Right?
A. They do have significant access to us, yes.
Q. They have access to you?
A. Yes.
Q. Have you ever testified differently?
A. They have access to us, but in different settings. In other words, industry or product-based reps can come to the operating room. They always have been able to, and they still are able to.
Q. So you see Ethicon representatives actually in the operating room at the university when a TVT's being implanted?
A. We don't see them now. We don't see -- we just don't see reps from them. I haven't seen an Ethicon rep in years.
Q. Why not?
A. I don't know. But they are allowed to. We have other device reps that are in the OR all the

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time.
Q. I guess what I'm asking you is, what information did you have from Ethicon up until the time you were hired as an expert?
A. The IFU.
Q. What else?
A. Certainly, the -- our classic core textbooks, articles, meetings that we've attended.
Q. Did you have textbooks from Ethicon?
A. No. The core textbooks of urology.
Q. Okay. I'm specifically asking you about Ethicon documents. There are things that are called slick sheets, are you familiar with those?
A. What sheets?
Q. Slick sheets.
A. What's that?
Q. Okay. The fact that you're asking about it must mean that you don't have it. Those are laminated instructions.
A. No.
Q. So Ethicon didn't give you those?
A. No.
Q. You basically had the instructions for use, and that was the only document, per se, that was

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given to you by Ethicon in connection with the TVT device, right?
A. Yes.
Q. In other words, you were never given the seven-year Prolene dog study, right?
A. No.
Q. You were never given PowerPoints, for example, that might have been put together on the concept of degradation of polypropylene?
A. No.
Q. None of that information was shared with you, right?
A. That's correct.
MS. ROBINSON: And just so the record's clear --
Q. Let me finish, and then you can make it.
And just to be clear, that information that is included on your reliance list was only provided to you after you agreed to testify on Ethicon's behalf?
A. Yes.
MS. ROBINSON: That was my question. You keep saying "never" and so forth.
MR. WALLACE: I was going there.

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Can you mark this as an exhibit?
(Deposition Exhibit No. 5 was marked for identification.)
Q. You've been handed Exhibit 5. Do you recognize that as a set of instructions for use for the TVT?
A. Yes.
Q. And it's in various languages. Do you see that?
A. Yes.
Q. Is this what would come in the package?
A. Yes. An instruction sheet comes in every package.
Q. And the instructions provide contraindications and warnings, correct?
A. It's supposed to.
Q. Well, with respect to the TVT, it came with that, correct?
A. I'm trying to find the English one. But it's supposed to.
Q. If you look at the Bates number ending in 383, and, actually, the page before it, 382 --
A. Yes.
Q. -- there's a list of contraindications and

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warnings.
A. Um-hmm.
Q. Do you see that?
A. Yes.
Q. It says that the Prolene polypropylene mesh will not stretch significantly. Do you see that?
A. Um-hmm.
Q. In fact, you would agree with me that mesh shrinks?
A. I don't know that it shrinks.
Q. Well, you've said that hernia mesh shrinks, right?
A. Yes.
Q. What's the difference between the mesh that's used in Ethicon's hernia meshes and the TVT?
A. Well, the data you're referring to is hernia meshes that were removed, so they determined that it contracted. But TVT mesh or vaginal mesh might behave differently.
Q. Do you believe that the properties are different?
A. Yes.
Q. How?
A. Well, hernia mesh is often thicker,

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other materials are used for it. It provides a different kind of support.
Q. Well, let's talk about Ethicon hernia mesh. Ethicon hernia mesh, isn't that the same thing as a TVT in terms of the material?
A. If it's polypropylene macropore and monofilament, then it should be the same.
Q. Okay. But you -- so in other words, you have no scientific basis to disagree with me that the TVT mesh contracts in the same way that the hernia mesh does?
A. There's other data that you can extrapolate, physical exam data, Q-tip testing, and how that doesn't result in a worsening of a patient's hypermobility after a TVT is placed looking out at a year, there's ultrasound data showing increase in visualization of the mesh because of hyperechoic particles of it that increase over time, suggesting that it doesn't contract, it probably remains the same, and it doesn't move, either.
Q. So you don't believe that a TVT mesh, once incorporated into -- as it incorporates into the tissues contracts at all?
A. As it incorporates in tissue, when placed

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normally, when placed according to the IFU and also placed according to what a reasonable surgeon should know how to do in terms of dissection and being away from the urethra and following a normal tissue plane and placing it tension-free, then yes, it shouldn't change.
Q. In other words, if it's put in properly, you do not believe that the TVT contracts?
A. I don't think so.
Q. Even when it's undergoing mesh incorporation with the tissues in the body?
A. It shouldn't contract.
Q. And yet, you still believe that hernia mesh contracts?
A. Yes.
Q. And you don't believe that the TVT Prolene mesh is the same kind of mesh that exists in the old hernia meshes at Ethicon?
A. I'm not sure of the specifics of whether it's the same or not. I don't do hernia surgery.
Q. What if they are?
A. Then they are.
Q. Does it change your opinion?
A. No.

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Q. Do you believe that tensioning affects shrinkage?
A. Placing something on tension that shouldn't be tensioned can have significant changes to outcome.
Q. Do you believe Ethicon is responsible to tell physicians how to properly tension the device?
A. They have.
Q. So you believe that they properly instruct physicians on how to do that?
A. I think their initial description of that was adequate, and I think the modifications that we have made from the original videos from 1998 and the original teachings of it have made it -- created other opportunities for us to tension --
Q. Who's "we"?
A. "We" as in urologists who are -- and urogynecologists and the gynecologists from the publications, presentations.
Q. What happens if the tension is not right?
A. What does that mean by "not right"?
Q. Too tight?
A. Too tight, then you can have a whole host of symptoms in patients.

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Q. What does "minimal tension" mean?
A. Minimal tension means that the graft is placed without any other tissue or structure impeding it, so it's not creating pressure on another structure, such as the urethra or the vaginal wall.
Q. That's a subjective measurement.
A. It's subjective, yes.
Q. And using the word "loosely" is also a subjective description, correct?
A. That's right.
Q. And if I understand your prior testimony correctly, you don't place the TVT laser-cut mesh any differently than you do the mechanical-cut mesh?
A. That's right.
Q. And you would tell me that it's also your testimony that whether or not it's laser-cut or mechanical-cut does not affect the tension?
A. It does not.
Q. So you disagree with Ethicon's own medical director on that?
A. I don't think it has any difference in my practice.

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Q. If the device is not tensioned correctly, do you believe that's the fault of the physician?
A. Yes.
Q. And you know that tension can cause scarring, and you want to avoid that because that can cause pain?
A. Yes, it can.
Q. Would you agree with me that overtightening is easy to achieve?
A. Oh, yes.
Q. Where is chronic pain listed in Exhibit 5?
A. I don't see that it is.
Q. It's not listed in the instructions for use that existed before 2015, right?
A. Right.
Q. And as an expert that's been hired by Ethicon to opine on the safety and efficacy of the TVT device, you would agree with me that the 2015 version of the IFU was much more complete when it comes to listing the complications and warnings that may be relevant to the TVT device, right?
MS. ROBINSON: Object to form.
A. I'd say it's a more lengthy list of

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complications. I'm not saying that it should or should not have been in the original version.
Q. Does the original version list dyspareunia as a risk?
A. No.
Q. Does it even use the word "dyspareunia"?
A. No. But that's understood. It's a pelvic surgery, and any pelvic surgery can have those risks.
Q. So you don't believe that a medical device company is obligated to put in the risks that are associated with this device?
A. The risks associated with that specific device that are different from other devices and/or other surgeries and ways that we do things.
Q. And you would agree with me that your opinion is different from any other physician's on that issue, correct?
A. I don't know that.
Q. You would agree with me that your opinion on that issue is different than the standards that apply to warnings, right?
A. No.
Q. You're not a warnings expert?

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A. I am familiar with warnings, yes.
Q. But you're not a warnings expert?
A. Is it on my CV that I am? No.
Q. I don't see it. I'm asking you, you're not a warnings expert, are you?
A. I'm knowledgeable about warnings.
Q. But are you a warnings expert, yes or no?
A. I can't answer that question.
Q. Why not?
A. I'm knowledgeable about warnings as they pertain to me.
Q. Why can't you answer that question?
A. I can't answer that question.
Q. Have you been hired to opine on the warnings in this case as a warnings expert or not?
A. Yes.
Q. You have?
A. Yes.
Q. You believe you have?
A. Um-hmm.
Q. And you believe that you're an expert with respect to the Ethicon warnings?
A. Yes.
Q. Why?

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A. Because these -- the warnings that are placed on us are warnings that are appropriate to this particular device, that are germane to this device. But there are other warnings that are not listed that could occur with this surgery or any other ones that are performed.
Q. And you realize that your testimony differs from the standards that apply to warnings, right? Because as a warnings expert that's been hired by Ethicon, you've done your due diligence, naturally, and have reviewed those standards, right?
A. Yes.
Q. And what are the standards?
A. There's a standard form when an IFU is put together. There's material on sections that need to be followed. But the material that's placed in there is under the discretion of the company itself with further conjunction.
Q. That's not true, is it?
A. What's not true?
Q. You are supposed to list all known risks. That's what the standards require, right?
A. All known risks related to that product.
Q. So your definition that it has to be only

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related to that product is inaccurate, correct? It does not match the standards?
A. No.
Q. You just said, Doctor, that all known risks related to the product have to be listed.
A. That are specific to that product and not other things that could be known by surgeons to do other procedures.
Q. And what's the name of the standard that you're citing to?
A. Citing to what?
Q. That requires that only risks relating to that product?
A. That's the Blue Book for looking at the FDA requirements.
Q. Death is listed with anesthesia, and that's not unique to anesthesia.
A. Maybe.
Q. So do you want to change your testimony?
A. No.
Q. So if the standard that you believe exists that in -- and controls this issue is different than your testimony, would you amend your testimony to reflect that of the standard?

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A. If I'm told of other information, I certainly would be happy to review it.
Q. Fair enough, Doctor. But what I'm getting at is, if your testimony directly conflicts with this standard, would you agree that the standard controls?
MS. ROBINSON: Object to form. He's asked and answered that question six times.
Q. He has not answered that question. And I'm going to ask the court reporter to read it back now, and ask you to restrict your comments.
Please read the question back.
(Record read.)
Q. Can you answer that question, yes or no?
A. I can't answer it yes or no. I need to review what the standard is or what you're referring to.
Q. Well, you cited the Blue Book. Are you familiar with the Blue Book?
A. I've looked at it.
Q. And all I'm asking is if your testimony conflicted with the Blue Book, would you or the Blue Book control?
A. The Blue Book controls.

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MR. WALLACE: Can you mark this, please?
(Deposition Exhibit No. 6 was marked for identification.)
Q. You've been handed what's been marked as Exhibit 6; is that right?
And you recognize that as a 2015 instructions for use, correct?
A. Yes.
Q. And if you look to page 5 -- actually, pages 4 and 5, you'll see that under "adverse reactions," "Acute and/or chronic pain" is now listed, right, on page 5?
A. Yes.
Q. And that was not in the prior instructions for use, right?
A. That's correct.
Q. And the chronic pain is different from transitory pain, right?
A. Yes.
Q. And "Pain with intercourse," which in some patients may not resolve, is listed in the 2015 IFU, but not in the prior IFUs, correct?
A. That's correct.

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Q. And the adverse reaction that says "one or more revision surgeries may be necessary to treat these adverse reactions" is listed for the first time in the 2015 IFU, correct?
A. That's correct.
Q. None of what I just read was in any prior version of the instructions for use, correct?
A. That's right.
Q. You are aware, in connection with your reliance list with documents, internal Ethicon documents that state that fraying is a defect, correct?
A. No.
Q. You haven't seen that?
A. No.
Q. Have you seen any documents concluding that mesh degrades?
A. No.
Q. So you haven't seen any internal Ethicon documents indicating that mesh degrades?
A. No.
Q. Did you ask for any?
A. No.
Q. Why not?

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A. Because it doesn't degrade.
Q. So you disagree with Ethicon?
A. I do.
Q. And you would agree with me that there are some very smart people at Ethicon?
A. There are.
Q. And you consider them your partners in healthcare?
A. My partners in healthcare --
Q. That's what you said earlier.
A. Sure. They're my partners in healthcare.
Q. And you expect them to give you accurate information?
A. Right. When it's pertinent.
Q. And you would agree with me that polypropylene mesh can chemically degrade?
A. No. I think it's conflicting. I certainly know that your experts have data that states that it may, and I can show you data that states that it doesn't.
Q. You don't recall saying that it's possible that polypropylene mesh can degrade?
A. I don't believe that it can have any significant degradation. Certainly, mesh can

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change.
Q. Let's change the questioning so I don't have to ask you 20 questions, and we're not arguing about it.
I'm going to ask you a more basic question. Putting aside whether you believe it has clinical relevance, do you believe that mesh can chemically degrade?
A. I think mesh can degrade. I don't know that it can degrade chemically.
Q. In any event, you believe that mesh can degrade, but it is also your opinion that that has no clinical relevance?
A. Yes.
Q. So you disagree with any Ethicon documents or any literature anywhere that suggests that degradation can cause pain in a person with mesh?
MS. ROBINSON: Object to form.
A. I'd have to see those documents in specific of what you're referring to.
Q. Well, why haven't you looked at them? They've been provided to you by Ethicon.
A. I've looked at material that I think is pertinent for each case.

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Q. Well, you're giving a general opinion about the TVT, right?
A. I'm giving a general opinion about the TVT, yes.
Q. And you agree with me that there are people that have opined for Plaintiffs that mesh degrades and has clinical relevance?
A. They believe that it does, yes.
Q. And you're aware of case reports, for example, that demonstrate that the TVT is often taken out in pieces?
A. Yes.
Q. Yet is it still your opinion, knowing all of that, that you didn't think it was relevant to review degradation documents?
A. I didn't say I didn't review degradation documents. What I'm telling you is that I don't believe that the information that your experts suggest is clinically relevant, and I have the documentation that believes otherwise.
Q. Did you see any documents where Ethicon believed that degradation might affect erosion rates?
A. No. I don't know of that.

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Q. Would it surprise you to know that that was investigated by Ethicon?
A. I'm sure that they investigated a lot of things.
Q. Do you believe that those specific effects of polypropylene degradation on erosion rates is known?
A. I don't think it's known completely, no.
Q. Do you agree with Ethicon if it said degradation is a process which initiates after a few days postimplant?
A. No.
Q. Have you seen any documents that conclude that, any animal studies, for example?
A. That degradation occurs postimplant? There have been studies of dogs, there's some studies -- there's animal studies that people have looked at.
Q. Anything else?
A. There have been some mesh removal studies, but I don't think that there are -- even the ones that your own experts cite are not conclusive in saying that there truly is degradation.
Q. You don't know what additives are in the mesh, right?

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A. No.
Q. And you haven't undertaken an investigation to understand the process of degradation, right?
A. I've taken an effort to understand the process, yes.
Q. What is it?
A. What is what process?
Q. Well, you've said you've undertaken an effort to understand the process, so why don't you tell me what the process is.
A. Degradation would imply that there's breakdown of mesh fibers, okay, and that could be visualized on a specimen. So, certainly, you'd have to remove mesh to look at the fibers and see if that were the case. The problems with that is that studies that are often quoted were removed to patients who have had pain or problems or infection, so we don't know what happens in mesh that's not removed in normal people. So that's certainly one of the problems.
The other problem is that even within those studies, the type of reactions that occur are not well understood or supported. Further, the tissue that you're removing, you're not just removing

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mesh; you're removing tissue with the mesh, so pulling it, stretching it, changing its configuration is going to change what that mesh looks like under the microscope.

Further, looking at things like formalin and how that has been used, there have been studies that show that formalin may cause degradation, but there are others that specimens were preserved with formalin that showed no change in it, so. . .

Q. What are the studies that show formalin causes degradation?

A. Let me take a minute. I don't remember the specific study that showed that. I do remember reading that. But in some of the ones I looked at for degradation, there was no formalin effect. I think it's controversial. In a study by Woodruff, which looked at these meshes and also looked at biological grafts, these implants were actually placed in formalin.

Q. Okay. But I've asked you to explain the process as you understand it. Can you tell me anything chemically about the process of degradation?

A. Well, it may relate to oxidizers. It may

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relate to bacteria that theoretically could do that, although that's not clearly proven. Peroxide may have an effect on that as well, but that's not entirely clear. And if that is -- and if it does occur, it doesn't have any clinical significance.

Q. But you agree with me that there are documents and literature that show degradation in a mesh, a transvaginal mesh that has been removed for pain?

A. There are documents that show that.

Q. There are -- there's literature that shows that, too?

A. There are documents that show that.

Q. And just so we're on the same page, documents also means literature in your answer, correct?

A. They're papers. They're papers.

Q. Peer-reviewed literature?

A. Yes.

Q. Thank you. You've seen the AUGS and SUFU statement, right?

A. Yes.

(Deposition Exhibit No. 7 was marked for identification)

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Q. You've been handed a document that's been marked as Exhibit 7. Do you recognize it?

A. Yes.

Q. If you look at the bottom, you'll see the statement that "'the safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one year.'"

Do you see that? The very bottom of the first page?

A. Yes.

Q. Is this what you give your patients?

A. I don't give them that, no.

Q. You referenced earlier, though, a statement?

A. Yes.

Q. About the position statement that you provide to your patients.

What do you mean by that?

A. With information from the position statement, which is included further here, which show the justifications. I provide them with the justifications.

Q. Okay. So in other words, you took the justifications on page 2, which provide the reasons

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why polypropylene mesh should be used and give it to your patients?

A. I discuss each of these with them, yes.

Q. When you say "each of these," there are four reasons?

A. Right.

Q. Do you believe you're an advocate for the use of mesh?

A. I am.

Q. And so in providing this to your patients who may be considering this procedure, you're being an advocate for mesh?

A. Yes.

Q. And would you agree with me that showing the safety and effectiveness of a product up to one year is not a long-term safety study?

A. That's correct.

Q. And would you agree with me that every one of the authors that are listed on Exhibit 7 have been paid by industry?

A. In what sense have been paid by industry?

Q. Well, you know who Dennis Miller is, right?

A. Sure.

Q. Who is he?

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A. He's on Saturday Night Live.
Q. Who else is he?
A. Actually, I don't know Dennis Miller.
Q. You don't? Do you know if he has anything to do with mesh?
A. I don't know, no.
Q. So wouldn't you want to know if those people -- I mean, we talked about bias earlier?
A. Right.
Q. Do you think that if somebody was given millions of dollars as a result of mesh, do you think that that might affect their opinion?
A. It might.
Q. Wouldn't you want to know, at least, wouldn't you want it to be disclosed?
A. Well, at the time that these positions statements have come about, this is 2014, so we've all had disclosures of each of us through the AUA and through AUGS for members. You know, we have disclosures that we have to put on our Web site, so I would expect that these people, if they are getting funds, that they are disclosed in their industry relations.
Q. And it wouldn't surprise you to learn that

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every single one of them are connected to the mesh industry in some way, right?
A. It wouldn't surprise me, no.
MR. WALLACE: Please mark this one.
(Deposition Exhibit No. 8 was marked for identification.)
Q. Can you look at Exhibit 8, please. Do you recognize it?
A. I do not, no.
Q. Have you seen it before?
A. I have not.
Q. Do you know whether or not it's included in your reliance list?
A. I don't believe that it is. I don't recall seeing this document in this form in this e-mail.
Q. Have you looked at every single document on your reliance list?
A. I've looked at the vast majority of them, yes, but not each and every one of them. They're there for me so I can look at them as I need to.
Q. You would agree with me, if you'll look at the middle of the way down the page, you'll recognize some of the names. Dan Lamont, Gene Kammerer. Do you see those names?

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A. Yes.
Q. You recognize those as people who are pretty high up at Ethicon?
A. No. I don't know any of those names.
Q. You don't?
A. No.
Q. Do you know anyone within Ethicon?
A. No.
Q. Have you as a result of being hired by Ethicon taken it upon yourself to talk to any employees of Ethicon?
A. No.
Q. You've had the opportunity to, didn't you?
A. I'm sure I could have.
Q. Wouldn't you, if you came across -- we talked earlier about the fact that you've seen documents that say particle loss is one of the reasons for a laser-cut mesh.
Wouldn't you want to know more about that and what Ethicon concluded internally about that issue?
A. If Ethicon had issues that were clinically relevant, they would be brought to all of us as clinicians, since we're users of the product. The

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field team would come out to us -- the people would come to us, if they were clinically relevant. The reason they haven't is because it's not clinically relevant.
Q. Well, look at the middle of the page. It says, "Particle loss is the reason why TVT wants to use laser-cut mesh to eliminate particle loss (which is critical to quality)."
Do you see that?
A. I do.
Q. Do you agree with that statement?
A. I've not seen that as an issue, okay? I've also looked at mesh as it comes out of the package from the very beginning. I've not seen any -- even any threads that are lost off of any mesh over the years as we take it out and check its expiration date and other opinion of it. So to me, I don't see any difference between laser-cut and mechanical-cut mesh.
Q. Have you seen any studies that conclude otherwise?
A. No.
Q. You haven't?
A. No.

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Q. Have you seen any documents where the -- one of the coinventors of the TVT product believes that they won't use laser-cut mesh?
A. No.
Q. You haven't seen that?
A. No.
Q. Wouldn't that affect your opinion?
A. No.
Q. Why not?
A. Because I have 15 years of opinion, and as I told you, I didn't know until 2007 that there was a change, that there was any difference between these two, because it has no clinical effect in our practice. It did not change any of the problems, or. . .
Q. And that's solely based upon your own observations, right?
A. Well, it's also been based upon presentations at meetings. I have not heard any discussion about this difference until this has been brought up most recently through these processes.
Q. Have you seen any documents that conclude that the TVT could curl and rope, thereby reducing

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the surface area of the mesh under the urethra and increasing the pressure in that area?
A. No.
(Deposition Exhibit No. 9 was marked for identification.)
Q. Again, wouldn't you want to know that information if Ethicon had it?
A. Unless it's clinically relevant, I don't need to know this.
Q. Well, isn't it clinically relevant if the mesh can curl and rope and increase pressure under the urethra and cause pain in that area?
A. I haven't opined to you that this is the case in all patients.
Q. I said the issue is whether it can, right?
A. Can mesh curl and rope? I've not seen that that's -- that that occurs clinically.
Q. Wouldn't you want to know if you're talking about the safety and efficacy of a mesh device, a TVT, what Ethicon's own opinions are about that issue?
A. Only if they're clinically relevant. I have my own -- after 15 years, I have my own opinions.
Q. But your opinions doesn't necessarily make

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you the be-all-end-all on that, wouldn't you agree?
A. That's right.
Q. So -- okay. So fair enough. You just don't consider Ethicon documents in that regard one way or another to support your opinion?
A. These have no effect on my opinion whatsoever.
Q. And you're just -- in other words, you just, because of your own experience, you're just not going to consider them?
A. I don't have -- no.
MS. ROBINSON: Object to form.
A. I don't need to consider them.
Q. Even if they disagree with your viewpoint?
MS. ROBINSON: Object to form. Asked and answered.
A. The way this is written and the way this is theorized can apply just as easily to mechanically-cut mesh or the laser-cut mesh. The issue with retention can be exactly the same. If it's going to cause retention, okay? And the issue with roping or curling would be on the ends of it, if it weren't placed in a tension-free fashion and it weren't evaluated carefully upon

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completion of the procedure to know that it was -- whether it was placed properly.
And it also helps you -- it helps you, too, by looking where the pressure localizes --
MS. ROBINSON: Not a question.
MR. WALLACE: Can you mark that?
(Deposition Exhibit No. 10 was marked for identification.)
Q. Can you please look at Exhibit 10 and tell me if you have seen it before?
A. I have not, no.
Q. You've never seen the PA Consulting Group --
A. No.
Q. -- PowerPoint?
A. Nope.
Q. Do you realize that this PowerPoint concludes that mesh can degrade, and it talks about erosion in connection with degradation?
MS. ROBINSON: He said he hasn't seen it.
A. I haven't seen it, so if you want to talk --
Q. Well, you may have been told about it?
A. No. I've never been told about this document.

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Q. Well, don't you want to know if information that Ethicon has about degradation and its effect on erosion, wouldn't you want to consider it, or are you just going to sit here and say that your 15 years of experience is what matters?
A. I'm going to say that in my 15 years of experience and in materials that I have reviewed and seen, that I don't think there's any clinical relevance to degradation and its relationship to erosion.
Q. So in other words, if that document or other documents like it conclude otherwise, you're just not going to consider them?
A. I have to read this. I have not read this. If you want to point me to a specific portion of it --
Q. Okay. I'm going to let you read it, and please do, but just, my question is more basic than that.
If -- assuming this document is contrary to your opinion, you're just not going to consider it because you're going to rely more on your 15 years of experience, right?
A. I'm going to read it. I'll read anything

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that's provided to me, but that doesn't mean my opinion will change.
Q. Go ahead.
A. Well, this is going to take me an hour to read all these slides, so I would suggest in the essence of time that you point to me what you want me to look at specifically.
Q. Why don't you look at the second page, and you'll see in the middle of the page it says "Mesh erosion is complex, and the clinical studies do not give a clear picture due to the diversity of variables."
Do you agree with that statement?
A. That's true.
Q. Do you agree with the statement underneath that, that says that "the causes of mesh erosion are not well understood"?
A. They're not well understood, yes.
Q. Do you agree with the last bullet point in that same slide in the middle of the page that says "The situation is further complicated by known factors, such as the propensity of polypropylene (PP) to suffer degradation, and the specific effects of polypropylene degradation on erosion

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rates is not known"?
A. I think the degradation of polypropylene is actually known. It's been studied. It doesn't degrade. It's not been uniformly shown that it degrades in all studies.
Q. Would you agree with the slide underneath it that says "Mesh erosion is lower in polypropylene meshes used in transabdominal surgery than in transvaginal surgery"?
A. That's actually -- well, when you refer to transabdominal surgery, what do you mean by that?
Q. I'm just asking you to look at the slide and see whether or not you agree or disagree with the statement.
A. Well, transabdominal surgery is very big. Are we talking about, say, sacrospinous ligament fixation? Are we talking about abdominal sacrocolpopexy? What are we talking about?
Q. So you just don't know?
A. Well, it doesn't say. It's a very vague statement. And, actually, it is lower with polypropylene meshes used in vaginal surgery than transabdominal surgery.

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Q. Can you look at page 6, please, the bottom slide on the left? Do you agree or disagree with this statement that "polypropylene can suffer from degradation following implant"?
A. I disagree.
Q. Look at the rest of the slide. Can you read that? Look at the first bullet point.
I asked you earlier about animal studies in connection with polypropylene.
A. Yes.
Q. And you'll see that the statement says that there are animal studies that show that degradation occurs a few days after post-implant, or at least starts to occur.
Do you agree with that statement?
A. In that study, I mean, but that's an animal study. It's not a human study.
Q. And what's the science behind your basis to conclude that there's a difference?
A. Well, I can show you data. I can show you the Woodruff study, which actually looked at polypropylene mesh and shows that it didn't degrade in meshes that were removed compared to autologous slings that actually did show the

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degradation.
Q. Woodruff was an animal study?
A. No, Woodruff was a human study.
Q. And you're also aware of other studies that say that based upon explants that mesh degrades?
A. As I said, it's not clear. I've mentioned to you and cited a very important study that shows that it doesn't degrade.
Q. And you conversely also understand that there are studies that show that it does?
A. Hence the reason why there's controversy.
Q. And wouldn't you want to know what Ethicon has to say about that issue?
A. If it were important, they would have told me a long time ago.
Q. But you didn't see this document before today, did you?
A. No. And it doesn't change my opinions now seeing the document.
Q. Why?
A. Why what?
Q. Why doesn't it change your opinions?
A. Because if there were a significant issue with this product that all physicians needed to

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know about that was different from what they learned from their skills and training and education that was unique to this product and not any other one, they certainly would have told us information in a timely fashion.
Q. And even though you agree with the part of the PowerPoint that I showed you that the concept of mesh erosion, for example, and the studies associated with it are complex and difficult to understand?
A. Um-hmm. They're certainly complex, yes.
Q. Well, isn't that the most common complication associated with mesh?
A. Erosion?
Q. Um-hmm.
A. Actually, no, not that I see.
Q. What are the most common complications?
A. Most common complication that I see is voiding dysfunction, urgency and frequency, urge incontinence, pelvic pain. I actually see very few mesh extrusions, and that's well documented. The extrusion rate for vaginal mesh is less than 1 percent on average.
Q. Please turn to page 8 of your report in the

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Hendrix matter. And I'm specifically referring to the general part of your report.
What do you mean when you use the word "dense fibrosis" on page 8?
A. Dense means thick. Fibrosis means scarring. So thick scar.
Q. I'm trying to use a lot of "it's important to note" type of paragraphs, so I'm trying to figure out what you're really saying in this paragraph. Can you try to explain that to us?
A. Yeah. And, actually, this is an interpretation via the "Discussion" section of the Wang paper, okay? And this -- Wang, et al. These are the authors stating that the inadequate vaginal tissue coverage during the operation, mesh rigidity, propensity for an injury at a nearby site, or localized inflammation is somewhat plausible. So, in other words, it's localized inflammation is what you're referring to now.
In patients who have complete epithelia-lization of the mesh -- in other words, the vaginal wall is well healed underneath -- and then their mesh was removed for some other reason, like they wanted it removed or had some other procedure,

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that even in these patients who don't have issues, they have -- some of them have had a foreign body reaction, fibrosis, and perivascular mononuclear cell infiltrate, which means they had chronic inflammatory evidence.
So the point is, the inflammation that is seen as a histologic reaction can be present in slings that have extruded, which they talked about earlier. Epithelialized, in other words, maybe they had an erosion, it was cut, and then the vaginal tissue healed, or it looked completely normal but they removed it for some other reason. That's what that paper means.
Q. Look at page 9. And just for clarification, your report says three. You thought that maybe two patients that had mesh extrusion.
You used the word "three" on page 9. Do you see that?
A. Yeah.
Q. Is it three or two?
A. It might be three. Again, this is -- you know, off the top of my head.
Q. Well, you want to be careful, right?
A. Right.

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Q. It was just off the top of your head; is that what you said?
A. Yes.
Q. When you say "off the top of your head," meaning, you believe, off the top of your head there's been only three patients that you're aware of?
A. That I'm aware of that had TVT mesh erosion, yes.
Q. And why did you look at the mesh under a magnifying glass?
A. Where are we seeing that?
Q. In that same paragraph.
A. Well, the thing when you have a lot of mesh is -- and certainly, there's a lot of different theories about what happens to mesh, looked at pathologically, and, you know, I thought it would be interesting to just look and see. Actually, we're looking even with optical loupes to look and see what happens.
Usually, we're doing it when we're putting them in. So in other words, after we're finished, I put on my loupes and just look and see how the mesh lays. And I've not seen any differences or

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any problems associated with it.
Q. You'd agree with me that there are peroxides present in the vaginal tissues?
A. Vaginal tissues or. . .
Q. Or vaginal space.
A. That's two different things. Is it in the vaginal space, i.e., the bacteria that are present within the lumen of the vagina, yes.
Q. And that's actually the area in which the TVT is?
A. No.
Q. Goes through?
A. No.
Q. You don't think so?
A. No.
Q. You don't think it's ever exposed to any clean -- or contaminated area?
A. Well, the vagina always has bacteria, and we know that in all surgeries that we do. But once that area is closed and there's complete epithelialization, there shouldn't be any type of infection that occurs in these meshes.
Q. But there's a possibility that -- of how this device is put in that it can be exposed to a

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contaminated field?
A. Contaminated in terms of what? Contaminated in terms of infection or we also talked about peroxides and other things?
Q. Sure. Let's just stay with peroxide.
A. Yes.
Q. And you would agree with me that where it sits, it's exposed to fibroblasts and neutrophils at points in time?
A. Let's go back to peroxidase, okay? Not all bacteria secretes peroxidase. Not all lactobacillus secretes peroxidase. And the peroxidase levels -- peroxide levels change in menopausal status with women.
Q. So all women are different?
A. So all women are different.
Q. So one woman might have more reactive oxidative species than another? Or she might have cells, for example, that secrete more peroxidase?
A. They might. But --
Q. You would agree with me?
A. Yeah. But that's probably not clinically relevant.
Q. Probably not?

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A. Probably not.
Q. In your opinion, based on what signs?
A. Based on just looking at degradation of mesh that was studied. Just looking at mesh that was removed. Looking at the Woodruff study, and looking at there was no degradation in that group that had TVT mesh removed.
Q. You would agree with me that there are some women that are called high responders, right?
A. What is a high responder?
Q. Meaning that they might have a greater inflammatory response than another woman because of their status in life, just how they're made?
MS. ROBINSON: Object to form.
A. It may -- it's -- probably is not that as their basis. They probably have an underlying condition, an underlying inflammatory condition, which is well known. Things like lupus and rheumatoid arthritis and other things. But that inflammation doesn't necessarily relate to what the bacteria in the vaginal canal are doing. That may just be their own immunogenicity.
Q. In other words, whether a woman secretes more peroxidase than another, you don't believe

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that that would have any clinical impact on their healing or the mesh?
A. No. It shouldn't have an impact on that. And, furthermore, the issue with bacteria shouldn't have any effect on it either, because in meshes that were removed, even in Clavet's work, when he looked at that, he couldn't conclude that there was bacteria present, even in a patient with acute inflammation, in group one, no bacteria genesis was noted.
MR. WALLACE: Can we go off for a minute?
(Off the record 2:43 p.m.)
(On the record at 2:45 p.m.)
MR. WALLACE: I have no further questions.
MS. ROBINSON: I have a couple follow-up.
CROSS-EXAMINATION
BY MS. ROBINSON:
Q. Dr. Zaslau, do you recall counsel's questions of you regarding whether you were an advocate for mesh?
A. Yes.

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Q. And you responded that you were; is that correct?
A. Yes.
Q. And what are you -- what does that mean to you, being an advocate for mesh? What does that mean for you?
A. It means that in my clinical experience of 15 years, in my teaching to residents, as such, and review of the literature that this is a procedure that has worked well in my hands with long-term efficacy.
Q. And as a result of that, when you counsel your patients and you talk to them about mesh, is this a product that you feel that you want to offer to them as a choice to use and help them with their stress urinary incontinence?
A. I do, yes.
Q. When you indicate that you're an advocate for mesh, does that correlate to being an advocate for industry?
MR. WALLACE: Objection to form.
A. I'm an advocate for mesh as a procedure. In my hands, it's worked and it's worked well. Do I support industry by using industry's

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products? Yes. Because without their products I wouldn't be able to do these surgeries.
Q. And you believe it's important for you to be able to offer these products to your patients?
A. Yes.
Q. You were asked some questions by counsel earlier about warnings and whether you were an expert in warnings.
Would you agree with me in this case that you've been asked to offer your opinion as to whether the information provided by Ethicon in its IFUs was sufficient for you as a physician and for physicians in general to use their product?
A. I think the information there is sufficient to use.
Q. But that's essentially what you've been asked to opine on; is that correct?
A. Yes.
Q. About how you and other physicians read IFUs and utilize them in your practice, correct?
A. Yes.
Q. Now, he was asking you more questions about the technical requirements of what goes in the IFU as to drafting and regulatory requirements and

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everything like that, correct?
A. Yes.
Q. You're not a regulatory expert, right?
A. I am not.
Q. And you're not holding yourself out to be one; is that correct?
A. Not at all.
Q. So with regard to the information for use, are the complications that you have seen in your practice consistent with the warnings listed in the "Adverse Reactions" section of the IFU, in particular, the exhibit from 2001?
MR. WALLACE: Objection to form.
A. It was sufficient, yes, but the other issues that had come in the other iterations were things that were already known to us. They were just included for other reasons.
Q. Counsel asked you whether chronic pain was listed in the IFU in 2001, and it was not, correct?
A. Right.
Q. And you indicated, I believe, in your response that you didn't feel that it was necessary for chronic pain to be listed; is that correct?
A. That's correct.

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Q. And why is that?
A. Because it's known to all surgeons who do any pelvic surgery that pain can result, and it could be chronic.
Q. So if I understand your testimony, it's based on the fact that individuals using the product are surgeons who operate in the pelvic floor, correct?
A. Yes.
Q. And those surgeons are aware that any surgery they do to correct stress urinary incontinence, a hysterectomy, or otherwise can result in having chronic pain, correct?
A. Yes, it can.
Q. And based on -- your testimony is based on your own practice, correct?
A. Yes.
Q. But you're also a teacher, correct?
A. Yes.
Q. Do you teach your students utilizing IFUs at times?
A. We review for the first time when someone does a procedure, I show them the IFU. There's nice pictures in it, pictorials, and also the

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step-by-step aspect of the procedure so they can have something to take home and see what they've done.
Q. And so the IFU is more than just a list of complications and adverse effects as counsel has discussed with you, correct?
A. Right, yes.
Q. And have you found the Ethicon's IFU with regard to the TVT and TVT-O products to have been adequate for describing the procedure, as well as the potential complications and risks of the procedure?
A. Yes.
Q. Have you ever expressed any concern about any complications that are not listed in the IFU?
A. No.
Q. When you have attended meetings of your colleagues, of other urogynecologists or other urologists or gynecologists, have they experienced or expressed concerns to you about warnings and complications that were not contained in the IFU unrelated to mesh litigation?
A. No.
Q. Counsel also asked you a laundry list of

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questions concerning degradation and its effect on erosion and extrusion of mesh, correct?
A. Yes.
Q. And he asked you a series of questions about whether Ethicon had shared with you certain documentation, studies, conclusions, and theories offered by its various company employees, correct?
A. Yes.
Q. You indicated that you're not -- that that kind of information isn't information that is information that's important to you in your practice; is that correct?
A. That's correct.
Q. And to a jury, that may sound like, "Well, Dr. Zaslau has his head in the sand. He just doesn't want to know anything."
Would you agree with me that that's what it sounds like?
MR. WALLACE: Objection to form.
A. I know that if there were anything pertinent, internally, regarding this procedure that Ethicon would have let physicians know immediately. Okay?
Q. So my question of you is with regard to

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degradation and that process.
A. Right.
Q. Degradation in and of itself, is it a complication?
A. No, it's not a complication.
Q. Does degradation have any impact in and of itself on the woman that you are treating?
A. No.
Q. So degradation insofar as it may be linked to mesh exposure or erosion, as counsel's been asking you about, do you have knowledge of that impact through the literature that you read, your experience, and association and communications with your colleagues?
A. Right.
Q. In other words, you know the mesh erosion and extrusion rates, correct?
A. Yes.
Q. And you read about that in the literature every day?
A. Yes.
Q. And it's been written about since mesh was first used way back in --
A. In 1998, or even before that with the other

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meshes, the other procedures. Right.
Q. Correct. To your knowledge, has degradation resulted in any new complication that was unknown to physicians who operate in the pelvic floor using mesh?
A. No.
MS. ROBINSON: That's all the questions I have.
REDIRECT EXAMINATION
BY MR. WALLACE:
Q. Would you agree with me that a woman said -- who now has chronic pain that has been associated with a TVT, who says that she was never told that she might have chronic pain, that's an unfortunate event, correct?
A. Yes.
Q. And you would agree with me that her physician, even going all the way back to 2001, should have told her about that, just like you've told your patients?
A. Physicians who do any pelvic surgery should warn the patient that chronic pain can happen from any procedure.
Q. And specifically from the TVT procedure?

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A. From any incontinence procedure.
Q. Right. And specifically from the TVT procedure, because I'm talking about the TVT?
A. Right. Then yes.
Q. Okay. And -- but you would also agree with me that a physician is entitled to rely on the instructions for use?
A. In part. And the remainder is from their clinical experience and education and teaching, coursework, lectures, meetings.
MR. WALLACE: I have no further questions.
MS. ROBINSON: I have nothing further. Thank you.
(At 2:54 p.m., the deposition concluded and signature was not waived.)

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C E R T I F I C A T E
STATE OF WEST VIRGINIA)

I, Faye Ann Lehman, a Commissioner in and for the State of West Virginia, do hereby certify that before me personally appeared STANLEY ZASLAU, M.D., who was by me first duly cautioned and sworn to testify to the truth, the whole truth and nothing but the truth in the taking of his oral deposition in the cause aforesaid; that the testimony then given by him as above set forth is a true record of the testimony given by the witness, and was reduced to stenotype by me in the presence of said witness and afterwards transcribed upon a computer.

I do further certify that this deposition was taken at the time and place specified in the foregoing caption and was completed without adjournment.

I do further certify that I am not a relative of or counsel or attorney for any party hereto,

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office on this 22nd day of March, 2016.

The foregoing certification does not apply to any reproduction of this transcript in any respect unless under the direct control and/or supervision of the certifying reporter.

____
Faye Ann Lehman, Commissioner
My Commission Expires May 20, 2020

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

STANLEY ZASLAU, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public